EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-11

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Stormwater Planning
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D. Analysis, Document, and Issue Paper Preparation

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/03/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Susan Julius (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8619 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-11

TITLE: Final Products -- Incorporating Climate Change into Stormwater Planning

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Specify Section & Paragraph SOW: Please select from the following:
D. Analysis, Document, and Issue Paper Preparation

PERIOD OF PERFORMANCE: *November 3, 2014 to 10/31/15*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the form of producing a final report and other outreach materials based on the results of three workshops held with municipalities in the Chesapeake Bay watershed last year to incorporate climate change into stormwater planning. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 0-11. The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of a final report based on the results of NOAA and EPA workshops held in the Chesapeake Bay and Great Lakes watersheds to incorporate climate change into stormwater planning. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA and over the course of 30 days, the Contractor shall schedule a series of twice-weekly conference calls (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Quality Assurance Project Plan (QAPP)

Because this rollover work assignment 1-11 is only deleting tasks from the previous work assignment 0-11, no new QAPP is needed. The previous QAPP, approved by the WAM and Quality Assurance Manager, is sufficient.

Task 3. Produce final report to submit to the NCA

The Contractor shall produce a draft report of the stormwater workshop results within 8 weeks of workplan approval, incorporating relevant information from other similar efforts where appropriate (e.g., if other similar workshops have been held, the Contractor shall draw on relevant information to enhance the content of the report). The Contractor shall submit a comment response (c-r) document with responses to internal review comments and a revised report within 4 weeks of receiving internal review comments on the draft document. The Contractor shall submit a c-r document with responses to external review comments and a final report with any necessary revisions within 4 weeks of receiving external review comments.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Calls	• 3 days after award of Work Assignment
Task 2. QAPP (previously approved)	• N/A
Task 3. Draft and Final Report	• Draft report due 8 weeks after workplan approval • Revised report and c-r document based on internal review comments due 4 weeks after receiving comments • Final report and c-r document based on external review due 4 weeks after receiving external review comments

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Task Order Manager (WAM)	**Alternate Task Order Manager (AWAM)**
Name: Susan Julius	Name: Britta Bierwagen
Office: ORD/NCEA/GCRP 1200 Pennsylvania Ave., NW (MC 8601P) Washington, DC 20460	Office: ORD/NCEA/GCRP 1200 Pennsylvania Ave., NW (MC 8601P) Washington, DC 20460
Phone: 703-347-8619	Phone: 703-347-8613
Fax: 703-347-8694	Fax: 703-347-8694
Email: julius.susan@epa.gov	Email: bierwagen.britta@epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

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EP-C-14-001	11/01/2013 To 10/31/2015	Stormwater Planning
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D. Analysis, Document, and Issue Paper Preparation

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/03/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$9,938.00	76
Total:	$9,938.00	76

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 01/20/2015	$9,938.00	76
Cumulative Approved:	$9,938.00	76

Work Assignment Manager Name: Susan Julius (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8619 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-12

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	ExpoFIRST
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B. Risk Assessment Methods

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:
Development of Exposure Factors Interactive Resource for Scenarios Tool (ExpoFIRST)

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Jacqueline Moya (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8539 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-12

TITLE: Development of Exposure Factors Interactive Resource for Scenarios Tool **(ExpoFIRST)**

Specify Section & Paragraph SOW: B. Risk Assessment Methods

PERIOD OF PERFORMANCE: CO Approval – October 31, 2015

I. PURPOSE

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) in developing an exposure scenarios tool.

II. BACKGROUND

In 2004, EPA/ORD/NCEA issued the document entitled *Example Exposure Scenarios*. The purpose of the document was to outline scenarios for various exposure pathways and to demonstrate how data from the 1997 version of the *Exposure Factors Handbook* could be applied for estimating exposures. A similar document focusing on childhood exposure was published in October 2014. Exposure scenarios are tools that help the assessor develop estimates of exposure, dose, and risk. An exposure scenario generally includes facts, data, assumptions, inferences, and sometimes professional judgment about how the exposure takes place. The example scenarios presented in the 2004 *Example Exposure Scenarios* document were selected to best demonstrate the use of the various key data sets in the 1997 *Exposure Factors Handbook*, and represented commonly encountered exposure pathways. An exhaustive review of every possible exposure scenario for every possible receptor population was not feasible and was not provided in the document.

Under WA-0-12, a beta version of the Exposure Factors Interactive Resource for Scenarios Tool (ExpoFIRST) was developed. The Exposure Scenarios Tool was designed to replace and update the 2004 *Example Exposure Scenarios* document using more recent information from the *Exposure Factors Handbook: 2011 Edition.* The tool allows users to develop a wider variety of scenarios than those provided in the 2004 document.

ESTIMATED LEVEL OF EFFORT:

III. STATEMENT OF WORK

A. Objective

The purpose of this work assignment is to continue the development of ExpoFIRST, improve its features, address internal and external comments, and produce final version of the tool. This tool will be a key addition to the Exposure Factors module developed for EPA-Expo-Box.

B. Specific Requirements

Task 1: Workplan

The workplan shall describe how the work in this PWS shall be performed, with a schedule, budget, level of effort, and qualifications of personnel. The workplan shall include a schedule of deliverables and interim deliverables. The workplan shall reference the Quality Assurance Project Plan (QAPP) that was approved under WA 0-12 on 5/15/14. Any amendments to the QAPP shall be submitted with the workplan for EPA approval.

Task 2: Address Comments from the WAM

Under WA 0-12, the contractor completed the development of the conceptual model (task 3) and the development of the prototype (task 4). The contractor shall address comments from the EPA WAM on the version delivered on 10/31/14. Comments may include any bugs found during the EPA WAM testing of the tool, comments on the text used in the notes and other instructions, implementation of features to enhance the model to make it more user friendly, implementation to enhancements to the export feature of the tool to include more details for a more complete report that includes the inputs and assumptions of each scenario, and any modifications to the algorithm and exposure factors necessary for accurate results.

Task 3: Development of the Final Version of the Tool

EPA will conduct an internal review of the tool and provide comments to the contractor. The contractor shall address the comments and produce a new version of the tool suitable for external review. The contractor shall produce a response to comments document summarizing how internal comments were addressed. The external review will be conducted by EPA under a separate contract. The contractor shall incorporate comments obtained from the external review and submit a final version of the tool for EPA clearance and publication. The contractor shall address any comments that may arise from management clearance. The contractor shall produce a response to comments document summarizing how external comments were addressed.

V. SCHEDULE OF DELIVERABLES

Task 1: A work plan and any amendments to the QAPP shall be twenty days after issuance. The WAM will review the work plan and will clarify any questions with the contractor. Within 7 days of approval of the work plan, the contractor shall hold a conference call with the EPA WAM.

Task 2: The contractor shall incorporate any comments from the EPA WAM and produce another version of the tool suitable for internal review 4 weeks after work plan approval.

Task 3: The contractor shall incorporate internal comments within 3 weeks of receipt and produce an external review tool. The contractor shall deliver the final tool 3 weeks after receiving external comments. More time may be allowed in consultation with the EPA WAM if comments are more significant than originally expected. If any comments arise from the management clearance process, the contractor shall address them within one week.

VI. Management Controls

1. The contractor shall certify there is no conflict of interest. The contractor shall provide the following conflict of interest certification in the workplan:

> I certify that, to the best of my knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to this work assignment exist. Personnel, who perform work

under this work assignment, or relating to the work assignment, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this work assignment have been reported to the Project Officer or are attached, if applicable.

2. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

3. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

4. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in the contract.

VII. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VIII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

X. Work Assignment Manager (WAM)

Jacqueline Moya
US EPA (8623P)
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Telephone #: (703) 347-8539
FAX #: (703) 347-8694
Email: moya.jacqueline@epa.gov

Alternate WAM
Linda Phillips
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
Telephone #: (703) 347-0366
FAX #: (703) 347-8690
Email: phillips.linda@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-12

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	ExpoFirst
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B. Risk Assessment Methods

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$27,579.00	340
Total:	$27,579.00	340

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 12/29/2014	$27,579.00	340
Cumulative Approved:	$27,579.00	340

Work Assignment Manager Name: Jacqueline Moya (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8539 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

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Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	ExpoFirst
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B. Risk Assessment Methods

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$27,579.00	340
This Action:	$14,156.00	162
Total:	$41,735.00	502

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 05/18/2015	$14,156.00	162
Cumulative Approved:	$41,735.00	502

Work Assignment Manager Name: Jacqueline Moya (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8539 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

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Work Assignment

Work Assignment Number: 1-12

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	ExpoFirst
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	B. Risk Assessment Methods

Purpose:
- [X] Work Assignment
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Period of Performance: From 12/07/2014 To 10/31/2015

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Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017	$41,735.00	502
This Action:	$16,497.00	196
Total:	$58,232.00	698

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 08/18/2015	$16,497.00	196
Cumulative Approved:	$58,232.00	698

Work Assignment Manager Name: Jacqueline Moya (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8539 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-13

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	EPA-Expo-Box
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III.C.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-13

TITLE: Technical Support for Revisions to EPA-Expo-Box (a toolbox for exposure assessors)

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: CO approval through 10/31/2015.

I. PURPOSE.

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) for revisions to EPA-Expo-Box (a toolbox for exposure assessors). This is a continuation of efforts conducted under work assignment 4-77 of contract number EP-C-09-009 and work assignment 0-13 of contract number EP-C-14-001.

II. BACKGROUND AND OBJECTIVES.

EPA-Expo-Box is an online toolbox for exposure assessors. It was developed by EPA's Office of Research and Development, National Center of Environmental Assessment (NCEA) to serve as a web-based compendium of exposure assessment tools. It is comprised of a series of Tool Sets, each containing modules that address exposure assessment topics. Toolbox modules contain descriptions of the topics and links to exposure assessment resources including databases, models, guidance documents, and other resources for exposure assessors. A search interface allows users to identify resources using keywords or topics. EPA-Expo-Box was released in Fall 2013, but will require periodic maintenance to ensure that its content and tool links remain current. Technical assistance will be required for addressing user comments and updating EPA-Expo-Box as needed.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of five tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

Deliverable 1: The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

Task 2. The contractor shall assist in addressing comments on EPA-Expo-Box.

EPA-Expo-Box was released to the public in Fall 2013. EPA received and addressed comments on the toolbox subsequent to its release, but anticipates receiving additional comments from users. Reviewing and addressing comments as they are received is expected to be an ongoing process.

The contractor shall assist EPA in reviewing the comments received, and formulating plans for addressing reviewer comments. The contractor shall review comments provided by the COR. **Within 1 week after receiving comments from the COR**, the contractor shall arrange a conference call with the COR to discuss the comments and the next steps for making revisions to the toolbox. The contractor shall prepare and submit to the COR draft responses **within 2 weeks of the COR assigning issues or topic areas** that will need to be addressed. For the purpose of preparing the work plan and cost estimate for this work assignment, the contractor shall assume that there are 5 key issues to be addressed. The list of comments and their resolution that was developed under work assignment 0-13 of this contract shall continue to be maintained in order to track revisions made to the toolbox. This list will include key issues as well as broken links and other minor corrections.

Deliverable 2a: The contractor shall arrange a conference call with the COR **within 1 week after the receiving comments from the COR**.

Deliverable 2b: The contractor shall prepare draft responses to the issues **within 2 weeks of being assigned by the COR**.

Task 3. The contractor shall assist in updating EPA-Expo-Box content

EPA's Guidelines for Human Exposure Assessment are currently being revised. Because EPA-Expo-Box was developed to be consistent with the 1992 Guidelines, it will need to be updated when the revised guidelines are released. Additional revisions may be needed to reflect updated EPA policies or procedures. The contractor shall identify areas within EPA-Expo-Box that will require revision and provide suggestions for implementing these changes to the toolbox. The contractor shall provide the COR with a detailed list of suggested revisions **within 4 weeks of being notified by the COR that the revised guidelines or other new policies or procedures are available.**

Deliverable 3a: The contractor shall provide the COR with a detailed list of suggested revisions **within 4 weeks after being notified by the COR that the revised guidelines or other new policies and procedures are available.**

Task 4. The contractor shall assist in developing new toolbox content.

The contractor shall prepare draft content for a topic not currently covered by EPA-Expo-Box. The topic may include something suggested by a toolbox user or that selected by the EPA WAM. The content for the topic area shall include text to provide an overview of the topic, links to relevant tools, and graphics, as needed. For the purposes of developing the work plan and cost estimate for this work assignment, the contractor shall

assume that they will be asked to develop content for 1 new topic area that will be incorporated into the toolbox as either a module, sub-module (i.e., tab within module), or Quick Finder topic. **Within 1 week after being assigned the topic area by the COR**, the contractor shall develop an initial outline for review and comment by the COR. After completing any necessary revisions to the outline, based on the COR's comments, the contractor shall develop draft content for the selected topic area. The draft content shall be submitted to the COR **within 3 weeks after receipt of the COR's comments** on the outline. The contractor shall revise the content, based on the COR's comments, and submit the final content **within 2 weeks of receipt of the COR's comments**. Final content shall be submitted in an electronic format (i.e., MS Word or other appropriate software, as designated by the COR) and shall be suitable for incorporation into the Expo-Box web-pages.

Deliverable 4a: The contractor shall submit an outline to the COR for the assigned topic area **within 1 week after being assigned the topic by the COR.**

Deliverable 4b: The contractor shall submit the draft content to the COR for the assigned topic, **within 3 weeks after receiving comments from the COR on the outline.**

Deliverable 4c: The contractor shall submit the final content to the COR for the assigned topic, **within 2 weeks after receiving comments from the COR on the draft content.**

Task 5. The contractor shall review and update the Master Tool List

A Master Tool List for EPA-Expo-Box was developed previously under work assignment 4-77 of contract EP-C-09-009 and updated under work assignment 0-13 of EP-C-14-001. The purpose of this Master Tool List is to provide a comprehensive listing of all the tools included in the toolbox, along with the descriptions, URLs, and key words associated with each tool. The Master Tool List also indentifies all of the Tool Sets, modules, and sub-modules within the toolbox where the tool is to be included. The Master Tool List forms the basis of EPA-Expo-Box's underlying data that will be used for the following 2 purposes:

(1) to populate tables within each of the Tool Set modules that tools relevant to that topic area; and
(2) to allow the toolbox to be searched using key words via a user-friendly graphical user interface.

The contractor shall conduct 2 comprehensive reviews of the links in the Master Tool List to identify and correct any broken links **at intervals to be designated by the COR in written technical direction**. Identification of outdated tools shall also be accompanied by suggested replacement links.

The contractor shall also revise and update the Master Tool List, as needed, to incorporate any new tools that have been identified from comments on the toolbox (see Task 2), from the revision of existing content (Tasks 3), and from the development of new content (Task 4). The contractor shall also ensure that any new or updated tools have been appropriately assigned to the various Tool Sets, modules, and sub-modules (many of the tools will be applicable in more than one module or sub-module), and that accurate tool descriptions and key words are included. The contractor shall submit all of the draft information necessary to revise and update the Master Tool List to the COR **within 2 weeks after completing Tasks 2, 3, and 4** for comment by the COR. **Within 1 week after receiving comments from the COR**, the contractor shall submit the final information necessary to update the Master Tool List.

Deliverable 5a: The contractor shall conduct 2 comprehensive reviews of the links in the Master Tool List **at intervals to be designated by the COR in written technical direction.**

Deliverable 5b: The contractor shall submit to the COR draft information necessary to revise and update the Master Tool List **within 2 weeks after completing Tasks 2, 3, and 4.**

Deliverable 5c: The contractor shall submit the final information necessary to update the Master Tool List to the COR **within 1 week after the receipt of the COR's comments on Deliverable 5a**.

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

.IV. TIME TABLE.

Task	Deliverable	Time frame
1a 1b	Establish communication via conference call	Within 1 week after receipt of work assignment
2a 2b	Review comments and conduct conference call Draft responses to issues or topic areas	Within 1 week of receiving comments from the COR Within 2 weeks of being assigned by COR
3a	Submit revised Tool Set content	Within 4 weeks of being assigned by COR
4a 4b 4c	Prepare outline for topic area Submit draft content Submit final content	Within 1 week of being assigned by COR Within 3 weeks of COR comments on outline Within 2 weeks of COR comments on draft
5a 5b 5c	Review toolbox links Submit draft information for Master Tool List Submit final information for Master Tool List	At intervals to be designated by COR Within 2 weeks after completing Tasks 2, 3, and 4 Within 1 week of COR comments

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).

3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.

4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager	**Alternate WAM**
Linda Phillips US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-0366 FAX #: (703) 347-8690 Email: phillips.linda@epa.gov	Jacqueline Moya US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-8539 FAX #: (703) 347-8694 Email: moya.jacqueline@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-13

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Expo Box
	Base X Option Period Number	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III. C

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$24,186.00	282
Total:	$24,186.00	282

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/13/2014	$24,186.00	282
Cumulative Approved:	$24,186.00	282

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-14

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Microbial Data Usability
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7779 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-14

TITLE: Development of Tool for Microbial Data Usability for Environmental Decision Making

Specify Section & Paragraph SOW: B2. Support research, development, and application of new risk assessment methods suitable for either conducting or evaluating cumulative risk, microbial risk, mixtures risk, dose-response assessment (including extrapolation to low dose), exposure assessment, and relevant uncertainty analysis.

Period of Performance: November 1, 2014 – October 31, 2015

I. OBJECTIVES

The main objective of this Work Assignment (WA) is to support a new U.S. Environmental Protection Agency (EPA) tool for determining data usability requirements needed for environmental data collection and analysis of microbial samples for decision making. The tool will provide microbial data collectors, analyzers, and decision makers a standardized basis for the required quality and quantity of environmental data sufficient to support risk-based remedial decisions.

II. BACKGROUND

The EPA-NHSRC was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, the EPA-NHSRC's Threat and Consequence Assessment Division (TCAD) is responsible for assessing potential exposures associated with the intentional release of hazardous and toxic materials including chemical, biological, and nuclear threat agents. TCAD is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of the TCAD is the applications of microbial environmental assessment methodologies utilized to support cleanup decision making regarding cleanup goals, treatment technology efficacies, and detection limits during biological contamination incidents.

The EPA developed the *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) to offer guidance for chemical (Part A) and radionuclides (Part B) data collection and analysis. However, there is currently no similar guidance for microbial samples available for the EPA responders and managers who lead the site data collection or for the personnel who must interpret the data analysis for the site decision makers.

III. TASKS

Task 1: <u>Establish Communication</u>

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the Work Assignment Manager (WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The contractor shall generate a workplan that follows on work completed in the first performance period, describing how tasks 2-6 shall be performed. The workplan shall

include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations.

Within the workplan, the contractor shall deliver to the EPA Work Assignment Manager - Contract Officer Technical Representative (WAM) a Project Management file outlining the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships.

The contractor shall ensure adherence in the workplan to the existing approved Quality Assurance Project Plan developed under the previous year funding (WA0-14).

Deliverables: Conference Call and Project Management file

Performance Standard: The contractor shall provide the draft workplan containing projected tasks' specifics requested within 30 days of award.

Task 2: Data Usability Guidance for Microbial Samples Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports

The contractor shall organize, manage, and summarize 4-6 technical working group meetings by webinar for the new guidance. In addition, it is anticipated that an annual meeting will be held in late spring to synthesize these technical work group meetings. This annual meeting will be organized with at most 20-30 attendees and may cover 2 days in length.

1. The contractor shall meet with the WAM to discuss substantive, procedural and process design issues and define the workgroup members and other potentially involved interests and parties and further refine qualifications for the service provider.

2. The contractor shall select a facilitation professional to act as service provider for this project in consultation with the WAM. The appropriate service provider for this project will have a background in group management, microbial environmental sampling, microbial data analysis, and/or risk assessment,

3. The contractor shall work with WAM to identify the goals and purpose of the meeting, the issues involved, group relationships and interactions, timing and schedule for reports or activities.

4. The contractor shall work with the WAM to propose a design and schedule for the meetings. Upon approval of the WAM, the contractor shall implement the design.

5. The contractor shall facilitate the meeting per the project design and assist participants in articulating their interests, identifying areas of agreement, and recommendations for additional studies. As facilitator, s/he shall keep the parties talking, listening, and moving--as much as possible-- towards the goal of the meeting and assist the group in overcoming impasse. **THE FACILITATOR WILL NOT TAKE POSITIONS ON THE MERITS NOR RECOMMEND TO THE GROUP WHAT THE SUBSTANTIVE RESOLUTION OF AN ISSUE SHOULD BE.**

6. The contractor shall provide a draft agenda to the WAM for the meeting after consulting the WAM on needs and goals of the meeting.

7. The contractor shall communicate as necessary in person, by phone, or in writing, with the WAM to ensure that issues and concerns have been communicated accurately and that everything is adequately prepared for the meeting. Material shall be provided for approval at least 5 business days prior to the meetings.

8. The contractor shall provide draft meeting summaries to the WAM and meeting participants per the approved project design.

9. The contractor shall provide meeting supplies and on-site support for the annual meeting.

10. The contractor shall write the annual meeting summary report per the project design. This may include collecting and incorporating comments, suggestions and changes from the parties, circulating drafts and managing discussion of comments, researching and providing information, data and recommendations to the parties, assisting in design of the document and guidelines for comments.

11. The contractor shall provide subject matter experts/panelists in the field of microbial risk assessment, microbial environmental sampling and lab analytics, and microbial data analysis. The subject matter experts shall perform the following tasks under the specific supervision of the WAM and the general direction of the workgroup participants:
    a. Review preliminary product proposals and background materials
    b. Serve as a technical panel member during the technical meetings.
    c. Generate written sections of the product as described below.

Deliverable: 3-7 Technical Expert Meetings and Meeting Reports

Performance Standard: The contractor shall facilitate the first meeting within 1 month after approval of work plan.

Task 3: Framework for Online Data Usability Tool for Microbial Samples in Decision Making

The contractor shall develop, revise, and update the data usability product for microbial samples based off of the expert working group input received during and after the technical meetings. The contractor shall provide scientific and technical support under the direction of the WAM for the development of this product. The proposed scientific and technical authors shall be primarily EPA personnel who provide specific knowledge, expertise and experience needed for the new product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the new product outline and some content at the working group meetings. The contractor shall provide subsequent drafts based off of input from the technical experts obtained from meetings. The contractor shall present any revisions and reviews of the draft product once reviewed by the workgroup.

The document framework will be built by the workgroup group. *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) shall be used as a primary reference point. It is

anticipated that the product will be an accessible web-based tool, built in modular format. The modules may include topics such as:

Module A: Data Planning
- A1 Problem Definition and Background;
- A2 Data Quality Objectives and Criteria.

Module B: Data Management (Generation, Acquisition, Reporting)
- B1 Sampling Process Design (Experimental Design);
- B2 Sampling Methods;
- B3 Sample Handling and Custody;
- B4 Analytical Methods;
- B5 Data Management

Module C: Quality Assessment and Oversight
- C1 Quality Assessments; and
- C2 Reports to Management.

Module D: Data Application
- D1 Data Review, Verification, and Validation; and
- D2 Reconciliation with User Requirements.

Deliverable: Draft Framework for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall revise the content of the proposed microbial data usability tool within 1 month after the third technical work group meeting. The contractor shall develop the draft framework for the web based tool for review during the face to face meeting. A revised draft of the web-based tool framework shall be completed within 2 months of the face to face meeting.

Task 4: Example Use of Framework for Data Usability Tool for Microbial Samples in Decision Making

The contractor shall use *B.anthracis* as an example to populate the data usability product for microbial samples based off of the expert working group input and current state of scientific knowledge. The contractor shall provide scientific and technical support under the direction of the WAM for the development of this product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the content according to the working group suggestions. The contractor shall provide subsequent drafts based off of input from the technical experts. The contractor shall present any revisions and reviews of the draft product to the WAM.

Deliverable: Example use for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall present an example of the Data Usability Tool for Microbial samples using B. anthracis within 1 month after the third technical work group meeting. A revised draft of the example shall be completed within 2 months of the face to face meeting.

Task 5: Sampling and Risk Assessment Research Needs of EPA Responders and Regions during Environmental Flooding Summary Report

The contractor shall complete the needs assessment of EPA responders and Regions conducted during the initial phase of this contract. Under the direction of the WAM. The contractor shall develop a set of research options for applicable EPA personnel. Research suggestions may include strengthening sampling protocols during or after flooding and/or the enhancement of risk assessment conducted from those samples. The contractor shall compile the research needs discussions into a final summary report. The contractor shall present possible research studies as a result of the summary report findings.

Deliverables: Final Research Needs Summary Report

Performance Standard: The contractor shall provide the final needs assessment report within 4 months after award. The contractor shall provide possible research studies within 6 months of the final needs assessment report.

Task 6: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WAM and the contractor to keep EPA-NHSRC updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to EPA-NHSRC on request within two weeks of the request.

The contractor shall also submit combined technical and financial monthly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of EPA-NHSRC. All documents or presentations associated with this project shall be cleared through EPA-NHSRC prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by EPA-NHSRC WAM prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to EPA-NHSRC. EPA-NHSRC shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to EPA-NHSRC WAM with responses and dispositions of comments.

All references cited in submitted reports and deliverables to EPA-NHSRC shall be provided to EPA-NHSRC either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to EPA-NHSRC. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by EPA-NHSRC, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in a compatible electronic format, such as EndNote as well as a paper hard copy of the references. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit monthly reports.

IV. PERFORMANCE PERIOD

The performance period is 12 months from the date of award.

V. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
1	Conference Call	Contractor shall provide the completed workplan within 30 days of award	WAM shall document whether receipt of workplan is timely and acceptable and provide technical revisions as required
2	Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports	Contractor shall conduct 4-7 (includes annual meeting) technical expert working group meetings and develop the associated meeting reports. Contractor shall conduct the first meeting within 1 month of the workplan and any revised QAPP approval.	WAM shall participate in these meeting identify any issues to be addressed in the research or future reports
3	Data Usability Tool for Microbial	The contractor shall develop the draft tool proposal at the within 3 months after approval of the workplan	WAM shall document the receipt of this proposal, and ensure it is timely and technically acceptable. Technical comments shall be

	Samples Proposal		provided through the WAM after review of the work group.
3	Data Usability Tool for Microbial Samples Draft Framework	The contractor shall develop the draft tool framework within 2 months after the annual meeting.	WAM shall document the receipt of this draft framework, and ensure that it is timely and technically acceptable. Technical comments shall be provided through the WAM after review of the work group.
4	Example Data Usability Tool for Microbial Samples	The contractor shall develop in conjunction with the tool framework a specific example of its use with *B. anthracis*. A draft shall be completed within 8 months of approval of the workplan.	WAM shall document the receipt of this example and ensure that it is timely and technically acceptable and provide technical comments as appropriate
5	Sampling and Risk Assessment Needs during Flooding	Contractor shall provide the Final Report within 4 months after award	WAM shall document the receipt of this report and manuscript, and ensure that it is timely and technically acceptable and provide technical comments as appropriate
5	Sampling and Risk Assessment Research Studies	Contractor shall provide the draft proposal for research studies within 5 months after the Final Needs Assessment Report	WAM shall document the receipt of this report and manuscript, and ensure that it is timely and technically acceptable and provide technical comments as appropriate
6	Revised Flooding Summary Report	Contractor shall revise Final Report, and provide a revised Final Report and disposition of comments no more than 10 months after award	WAM shall document the receipt of the report and manuscript, and ensure that it is timely and technically acceptable
6	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WAM shall document receipt of monthly reports and ensure that these are timely and acceptable
6	Meetings with WAM	Contractor shall have periodic meetings with the WAM as needed	WAM shall participate in these meetings and identify any issues to be addressed

VI. INTELLECTUAL PROPERTY

All methods, models and tools developed by the contractor and/or provided to the contractor under this WA is the intellectual property of the EPA-NHSRC. All data collected and analyzed under this WA is the intellectual property of the EPA-NHSRC.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any

external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent of real personal or organizational conflict of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT CONTRACT OFFICER TECHNICAL REPRESENTATIVE (WAM)

Cynthia Yund, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
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Work 513/569-7779

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior

to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document

"Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work
CRADA	Cooperative Research & Development Agreement

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-14

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Tool for Microbial Data
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B2

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7779 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-14

TITLE: Development of Tool for Microbial Data Usability for Environmental Decision Making

Specify Section & Paragraph SOW: B2. Support research, development, and application of new risk assessment methods suitable for either conducting or evaluating cumulative risk, microbial risk, mixtures risk, dose-response assessment (including extrapolation to low dose), exposure assessment, and relevant uncertainty analysis.

Period of Performance: November 1, 2014 – October 31, 2015

I. OBJECTIVES

The main objective of this Work Assignment (WA) is to support a new U.S. Environmental Protection Agency (EPA) tool for determining data usability requirements needed for environmental data collection and analysis of microbial samples for decision making. The tool will provide microbial data collectors, analyzers, and decision makers a standardized basis for the required quality and quantity of environmental data sufficient to support risk-based remedial decisions.

II. BACKGROUND

The EPA-NHSRC was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, the EPA-NHSRC's Threat and Consequence Assessment Division (TCAD) is responsible for assessing potential exposures associated with the intentional release of hazardous and toxic materials including chemical, biological, and nuclear threat agents. TCAD is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of the TCAD is the applications of microbial environmental assessment methodologies utilized to support cleanup decision making regarding cleanup goals, treatment technology efficacies, and detection limits during biological contamination incidents.

The EPA developed the *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) to offer guidance for chemical (Part A) and radionuclides (Part B) data collection and analysis. However, there is currently no similar guidance for microbial samples available for the EPA responders and managers who lead the site data collection or for the personnel who must interpret the data analysis for the site decision makers.

III. TASKS

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the Work Assignment Manager (WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The contractor shall generate a workplan that follows on work completed in the first performance period, describing how tasks 2-6 shall be performed. The workplan shall

include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations.

Within the workplan, the contractor shall deliver to the EPA Work Assignment Manager - Contract Officer Technical Representative (WAM) a Project Management file outlining the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships.

The contractor shall ensure adherence in the workplan to the existing approved Quality Assurance Project Plan developed under the previous year funding (WA0-14).

Deliverables: Conference Call and Project Management file

Performance Standard: The contractor shall provide the draft workplan containing projected tasks' specifics requested within 30 days of award.

Task 2: Data Usability Guidance for Microbial Samples Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports

The contractor shall organize, manage, and summarize 4-6 technical working group meetings by webinar for the new guidance. In addition, it is anticipated that an annual meeting will be held in late spring to synthesize these technical work group meetings. This annual meeting will be organized with at most 20-30 attendees and may cover 2 days in length.

1. The contractor shall meet with the WAM to discuss substantive, procedural and process design issues and define the workgroup members and other potentially involved interests and parties and further refine qualifications for the service provider.

2. The contractor shall select a facilitation professional to act as service provider for this project in consultation with the WAM. The appropriate service provider for this project will have a background in group management, microbial environmental sampling, microbial data analysis, and/or risk assessment,

3. The contractor shall work with WAM to identify the goals and purpose of the meeting, the issues involved, group relationships and interactions, timing and schedule for reports or activities.

4. The contractor shall work with the WAM to propose a design and schedule for the meetings. Upon approval of the WAM, the contractor shall implement the design.

5. The contractor shall facilitate the meeting per the project design and assist participants in articulating their interests, identifying areas of agreement, and recommendations for additional studies. As facilitator, s/he shall keep the parties talking, listening, and moving--as much as possible-- towards the goal of the meeting and assist the group in overcoming impasse. **THE FACILITATOR WILL NOT TAKE POSITIONS ON THE MERITS NOR RECOMMEND TO THE GROUP WHAT THE SUBSTANTIVE RESOLUTION OF AN ISSUE SHOULD BE.**

6. The contractor shall provide a draft agenda to the WAM for the meeting after consulting the WAM on needs and goals of the meeting.

7. The contractor shall communicate as necessary in person, by phone, or in writing, with the WAM to ensure that issues and concerns have been communicated accurately and that everything is adequately prepared for the meeting. Material shall be provided for approval at least 5 business days prior to the meetings.

8. The contractor shall provide draft meeting summaries to the WAM and meeting participants per the approved project design.

9. The contractor shall write the annual meeting summary report per the project design. This may include collecting and incorporating comments, suggestions and changes from the parties, circulating drafts and managing discussion of comments, researching and providing information, data and recommendations to the parties, assisting in design of the document and guidelines for comments.

10. The contractor shall provide subject matter experts/panelists in the field of microbial risk assessment, microbial environmental sampling and lab analytics, and microbial data analysis. The subject matter experts shall perform the following tasks under the specific supervision of the WAM and the general direction of the workgroup participants:
    a. Review preliminary product proposals and background materials
    b. .
    c. Generate written sections of the product as described below.

Deliverable: 3- Technical Expert Meetings and Meeting Reports

Performance Standard: The contractor shall facilitate the first meeting within 1 month after approval of work plan.

Task 3: Framework for Online Data Usability Tool for Microbial Samples in Decision Making

The contractor shall develop, revise, and update the data usability product for microbial samples based off of the expert working group input received during and after the technical meetings. The contractor shall provide scientific and technical support under the direction of the WAM for the development of this product. The proposed scientific and technical authors shall be primarily EPA personnel who provide specific knowledge, expertise and experience needed for the new product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the new product outline and some content at the working group meetings. The contractor shall provide subsequent drafts based off of input from the technical experts obtained from meetings. The contractor shall present any revisions and reviews of the draft product once reviewed by the workgroup.

The document framework will be built by the workgroup group. *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) shall be used as a primary reference point. It is

anticipated that product be web-based format. The modules may include topics such as:

Module A: Data Planning
A1 Problem Definition and Background;
A2 Data Quality Objectives and Criteria.

Module B: Data Management (Generation, Acquisition, Reporting)

B Sampling Methods;
B Sample Handling and Custody;

B Data

Module C: Quality Assessment and Oversight
C1 Quality Assessments; and
C2 Reports to Management.

Deliverable: Draft Framework for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall revise the content of the proposed microbial data usability tool within 1 month after the third technical work group meeting. The contractor shall develop the draft framework for the web based tool for review during the face to face meeting. A revised draft of the web-based tool framework shall be completed within 2 months of the face to face meeting.

Task 4: Example Use of Framework for Data Usability Tool for Microbial Samples in Decision Making

The contractor shall use *B.anthracis* as an example to populate the data usability product for microbial samples based off of the expert working group input and current state of scientific knowledge. The contractor shall provide scientific and technical support under the direction of the WAM for the development of this product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the content according to the working group suggestions. The contractor shall provide subsequent drafts based off of input from the technical experts. The contractor shall present any revisions and reviews of the draft product to the WAM.

Deliverable: Example use for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall present an example of the Data Usability Tool for Microbial samples using B. anthracis within 1 month after the third technical work group meeting. A revised draft of the example shall be completed within 2 months of the face to face meeting.

Task 5: Sampling and Risk Assessment Research Needs of EPA Responders and Regions during Environmental Flooding Summary Report

The contractor shall complete the needs assessment of EPA responders and Regions conducted during the initial phase of this contract. Under the direction of the WAM. The contractor shall develop a set of research options for applicable EPA personnel. Research suggestions may include strengthening sampling protocols during or after flooding and/or the enhancement of risk assessment conducted from those samples. The contractor shall compile the research needs discussions into a final summary report. The contractor shall present possible research studies as a result of the summary report findings.

Deliverables: Final Research Needs Summary Report

Performance Standard: The contractor shall provide the final needs assessment report within 4 months after award. The contractor shall provide possible research studies within 6 months of the final needs assessment report.

Task 6: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WAM and the contractor to keep EPA-NHSRC updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to EPA-NHSRC on request within two weeks of the request.

The contractor shall also submit combined technical and financial monthly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of EPA-NHSRC. All documents or presentations associated with this project shall be cleared through EPA-NHSRC prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by EPA-NHSRC WAM prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to EPA-NHSRC. EPA-NHSRC shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to EPA-NHSRC WAM with responses and dispositions of comments.

All references cited in submitted reports and deliverables to EPA-NHSRC shall be provided to EPA-NHSRC either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to EPA-NHSRC. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by EPA-NHSRC, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in a compatible electronic format, such as EndNote as well as a paper hard copy of the references. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit monthly reports.

IV. PERFORMANCE PERIOD

The performance period is 12 months from the date of award.

V. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
1	Conference Call	Contractor shall provide the completed workplan within 30 days of award	WAM shall document whether receipt of workplan is timely and acceptable and provide technical revisions as required
2	Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports	Contractor shall conduct 4-7 (includes annual meeting) technical expert working group meetings and develop the associated meeting reports. Contractor shall conduct the first meeting within 1 month of the workplan and any revised QAPP approval.	WAM shall participate in these meeting identify any issues to be addressed in the research or future reports
3	Data Usability Tool for	The contractor shall develop the draft tool proposal at the	WAM shall document the receipt of this proposal, and ensure it is timely

	Microbial Samples Proposal	within 3 months after approval of the workplan	and technically acceptable. Technical comments shall be provided through the WAM after review of the work group.
3	Data Usability Tool for Microbial Samples Draft Framework	The contractor shall develop the draft tool framework within 2 months after the annual meeting.	WAM shall document the receipt of this draft framework, and ensure that it is timely and technically acceptable. Technical comments shall be provided through the WAM after review of the work group.
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VIII. WORK ASSIGNMENT CONTRACT OFFICER TECHNICAL REPRESENTATIVE (WAM)

Cynthia Yund, Ph.D.
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Work 513/569-7779

APPENDIX A

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EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection,

generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work
CRADA	Cooperative Research & Development Agreement

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-14

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	Microbial Data Usability

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	B.2

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$149,975.00	1,193
Total:	$149,975.00	1,193

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 02/18/2015	$149,975.00	1,193
Cumulative Approved:	$149,975.00	1,193

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7779 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-14

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Microbial Sample Data
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B2

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7779 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

STATEMENT OF WORK, WA-0-14-001
EPA WORK ASSIGNMENT NUMBER 1-14

TITLE: Development of Tool for Microbial Data Usability for Environmental Decision Making

I. OBJECTIVES

The main objective of this Work Assignment (WA) is to support a new U.S. Environmental Protection Agency (EPA) tool for determining data usability requirements needed for environmental data collection and analysis of microbial samples for decision making. The tool will provide microbial data collectors, analyzers, and decision makers a standardized basis for the required quality and quantity of environmental data sufficient to support risk-based remedial decisions.

II. BACKGROUND

The EPA-NHSRC was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, the EPA-NHSRC's Threat and Consequence Assessment Division (TCAD) is responsible for assessing potential exposures associated with the intentional release of hazardous and toxic materials including chemical, biological, and nuclear threat agents. TCAD is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of the TCAD is the applications of microbial environmental assessment methodologies utilized to support cleanup decision making regarding cleanup goals, treatment technology efficacies, and detection limits during biological contamination incidents.

The EPA developed the *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) to offer guidance for chemical (Part A) and radionuclides (Part B) data collection and analysis. However, there is currently no similar guidance for microbial samples available for the EPA responders and managers who lead the site data collection or for the personnel who must interpret the data analysis for the site decision makers.

III. TASKS

Task 1: <u>Workplan</u>

The contractor shall generate a workplan that follows on work completed in the first performance period, describing how tasks 2-6 shall be performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards

and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations.

Within the workplan, the contractor shall deliver to the EPA Work Assignment Manager - Contract Officer Technical Representative (WAM) a Project Management file outlining the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships.

The contractor shall ensure adherence in the workplan to the existing approved Quality Assurance Project Plan developed under the previous year funding (WA0-14).

Deliverables: Workplan and Project Management file

Performance Standard: The contractor shall provide the draft workplan containing projected tasks' specifics requested within 30 days of award.

Task 2: Data Usability Guidance for Microbial Samples Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports

The contractor shall organize, manage, and summarize 4-6 technical working group meetings by webinar for the new guidance. In addition, it is anticipated that an annual meeting will be held in late to synthesize these technical work group meetings. This annual meeting will be organized with at most 0- 0 attendees and may cover 2 days in length.

1. The contractor shall meet with the WAM to discuss substantive, procedural and process design issues and define the workgroup members and other potentially involved interests and parties and further refine qualifications for the service provider.

2. The contractor shall select a facilitation professional to act as service provider for this project in consultation with the WAM. The appropriate service provider for this project will have a background in group management, microbial environmental sampling, microbial data analysis, and/or risk assessment,

3. The contractor shall work with WAM to identify the goals and purpose of the meeting, the issues involved, group relationships and interactions, timing and schedule for reports or activities.

4. The contractor shall work with the WAM to propose a design and schedule for the meetings. Upon approval of the WAM, the contractor shall implement the design.

5. The contractor shall facilitate the meeting per the project design and assist participants in articulating their interests, identifying areas of agreement, and recommendations for additional studies. As facilitator, s/he shall keep the parties talking, listening, and moving--as much as possible-- towards the goal of the meeting and assist the group in overcoming impasse. **THE FACILITATOR WILL NOT TAKE POSITIONS ON THE MERITS NOR RECOMMEND TO THE GROUP WHAT THE SUBSTANTIVE RESOLUTION OF AN ISSUE SHOULD BE.**

6. The contractor shall provide a draft agenda to the WAM for the meeting after consulting the WAM on needs and goals of the meeting.

7. The contractor shall communicate as necessary in person, by phone, or in writing, with the WAM to ensure that issues and concerns have been communicated accurately and that everything is adequately prepared for the meeting. Material shall be provided for approval at least 5 business days prior to the meetings.

8. The contractor shall provide draft meeting summaries to the WAM and meeting participants per the approved project design.

9. The contractor shall provide meeting supplies and on-site support for the annual meeting.

10. The contractor shall write the annual meeting summary report per the project design. This may include collecting and incorporating comments, suggestions and changes from the parties, circulating drafts and managing discussion of comments, researching and providing information, data and recommendations to the parties, assisting in design of the document and guidelines for comments.

11. The contractor shall provide subject matter experts/panelists in the field of microbial risk assessment, microbial environmental sampling and lab analytics, and microbial data analysis. The subject matter experts shall perform the following tasks under the specific supervision of the WAM and the general direction of the workgroup participants:
    a. Review preliminary product proposals and background materials
    b. Serve as a technical panel member during the technical meetings.
    c. Generate written sections of the product as described below.

Deliverable: 3-7 Technical Expert Meetings and Meeting Reports

Performance Standard: The contractor shall facilitate the first meeting within 1 month after approval of work plan.

Task 3: Framework for Online Data Usability Tool for Microbial Samples in Decision Making

The contractor shall develop, revise, and update the data usability product for microbial samples based off of the expert working group input received during and after the technical meetings. The contractor shall provide scientific and technical support under the direction of the WAM for the development of this product. The proposed scientific and technical authors shall be primarily EPA personnel who provide specific knowledge, expertise and experience needed for the new product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the new product outline and some content at the working group meetings. The contractor shall provide subsequent drafts based off of input from the technical experts obtained from meetings. The contractor shall present any revisions and reviews of the draft product once reviewed by the workgroup.

The document framework will be built by the workgroup group. *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) shall be used as a primary reference point. It is anticipated that the product will be an accessible web-based tool, built in modular format. The modules

may include topics such as:

Module A: Data Planning

A1 Problem Definition and Background;
A2 Data Quality Objectives and Criteria.

Module B: Data Management (Generation, Acquisition, Reporting)

B1 Sampling Process Design (Experimental Design);
B2 Sampling Methods;
B3 Sample Handling and Custody;
B4 Analytical Methods;
B5 Data Management

Module C: Quality Assessment and Oversight

C1 Quality Assessments; and
C2 Reports to Management.

Deliverable: Draft Framework for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall revise the content of the proposed microbial data usability tool within 1 month after the third technical work group meeting. The contractor

shall develop the draft framework for the web based tool for review during the face to face meeting. A revised draft of the web-based tool framework shall be completed within 2 months of the face to face meeting.

Task 4: Example Use of Framework for Data Usability Tool for Microbial Samples in Decision Making

The contractor shall use *B.anthracis* as an example to populate the data usability product for microbial samples based off of the expert working group input and current state of scientific knowledge. The contractor shall provide scientific and technical support under the direction of the WAM for the development of this product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the content according to the working group suggestions. The contractor shall provide subsequent drafts based off of input from the technical experts. The contractor shall present any revisions and reviews of the draft product to the WAM.

Deliverable: Example use for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall present an example of the Data Usability Tool for Microbial samples using B. anthracis within 1 month after the third technical work group meeting. A revised draft of the example shall be completed within 2 months of the face to face meeting.

Task 5: Sampling and Risk Assessment Research Needs of EPA Responders and Regions during Environmental Flooding Summary Report

The contractor shall complete the needs assessment of EPA responders and Regions conducted during the initial phase of this contract. Under the direction of the WAM. The contractor shall develop a set of research options for applicable EPA personnel. Research suggestions may include strengthening sampling protocols during or after flooding and/or the enhancement of risk assessment conducted from those samples. The contractor shall compile the research needs discussions into a final summary report. The contractor shall present possible research studies as a result of the summary report findings.

Deliverables: Final Research Needs Summary Report

Performance Standard: The contractor shall provide the final needs assessment report within 4 months after award. The contractor shall provide possible research studies within 6 months of the final needs assessment report.

Task : Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WAM and the contractor to keep EPA-NHSRC updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to EPA-NHSRC on request within two weeks of the request.

The contractor shall also submit combined technical and financial monthly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of EPA-NHSRC. All documents or presentations associated with this project shall be cleared through EPA-NHSRC prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by EPA-NHSRC WAM prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to EPA-NHSRC. EPA-NHSRC shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to EPA-NHSRC WAM with responses and dispositions of comments.

All references cited in submitted reports and deliverables to EPA-NHSRC shall be provided to EPA-NHSRC either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to EPA-NHSRC. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by EPA-NHSRC, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in a compatible electronic format, such as EndNote as well as a paper hard copy of the references. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit monthly reports.

IV. PERFORMANCE PERIOD

The performance period is 12 months from the date of award.

V. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
1	Workplan	Contractor shall provide the completed workplan within 30 days of award	WAM shall document whether receipt of workplan is timely and acceptable and provide technical revisions as required
1	Revised Workplan	Contractor shall revise workplan if required and submit this revised workplan no more than 30 days after receipt of revisions	WAM shall document receipt of revised workplan and ensure that it is timely and technically acceptable
2	Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports	Contractor shall conduct 4-7 (includes annual meeting) technical expert working group meetings and develop the associated meeting reports. Contractor shall conduct the first meeting within 1 month of the workplan.	WAM shall participate in these meeting identify any issues to be addressed in the research or future reports
3	Data Usability Tool for Microbial Samples Proposal	The contractor shall develop the draft tool proposal at the within 3 months after approval of the workplan	WAM shall document the receipt of this proposal, and ensure it is timely and technically acceptable. Technical comments shall be provided through the WAM after review of the work group.
3	Data Usability Tool for Microbial	The contractor shall develop the draft tool framework within 2 months after the annual meeting.	WAM shall document the receipt of this draft framework, and ensure that it is timely and technically acceptable. Technical comments

	Samples Draft Framework		shall be provided through the WAM after review of the work group.
4	Example Data Usability Tool for Microbial Samples	The contractor shall develop in conjunction with the tool framework a specific example of its use with *B. anthracis*. A draft shall be completed within 8 months of approval of the workplan.	WAM shall document the receipt of this example and ensure that it is timely and technically acceptable and provide technical comments as appropriate
5	Sampling and Risk Assessment Needs during Flooding	Contractor shall provide the Final Report within 4 months after award	WAM shall document the receipt of this report and manuscript, and ensure that it is timely and technically acceptable and provide technical comments as appropriate
5	Sampling and Risk Assessment Research Studies	Contractor shall provide the draft proposal for research studies within 5 months after the Final Needs Assessment Report	WAM shall document the receipt of this report and manuscript, and ensure that it is timely and technically acceptable and provide technical comments as appropriate
6	Revised Flooding Summary Report	Contractor shall revise Final Report, and provide a revised Final Report and disposition of comments no more than 10 months after award	WAM shall document the receipt of the report and manuscript, and ensure that it is timely and technically acceptable
6	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WAM shall document receipt of monthly reports and ensure that these are timely and acceptable
6	Meetings with WAM	Contractor shall have periodic meetings with the WAM as needed	WAM shall participate in these meetings and identify any issues to be addressed

VI. INTELLECTUAL PROPERTY

All methods, models and tools developed by the contractor and/or provided to the contractor under this WA is the intellectual property of the EPA-NHSRC. All data collected and analyzed under this WA is the intellectual property of the EPA-NHSRC.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent of real personal or organizational conflict of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT CONTRACT OFFICER TECHNICAL REPRESENTATIVE (WAM)

Cynthia Yund, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7779

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

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These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

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(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

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Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work
CRADA	Cooperative Research & Development Agreement

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-14

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Microbial Data Usability
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B. 2

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$149,975.00	1193
This Action:	$30,502.00	274
Total:	$180,477.00	1,467

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 07/31/2015	$30,502.00	274
Cumulative Approved:	$180,477.00	1,467

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7779 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-15

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	EVIDENCE TABLES
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 05/13/2015 To 10/31/2015

Comments:
Section A (Assessment Issues and Documents), Subsection 1 (Human Health Assessment Documents)

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2289 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-15

TITLE: PREPARATION OF EVIDENCE TABLES FOR THE IRIS DRAFT TOXICOLOGICAL REVIEW OF POLYCHLORINATED BIPHENYLS (PCBs): EFFECTS OTHER THAN CANCER (CAS NO. 1336-36-3)

Specify Section & Paragraph SOW: Section A (Assessment Issues and Documents), Subsection 1 (Human Health Assessment Documents)

PERIOD OF PERFORMANCE: CO award to 10/31/15

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment 0-15. The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of updating the existing draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer (hereinafter the draft Toxicological Review). Specifically, support will include developing evidence tables for the draft Toxicological Review on the potential non-cancer health hazards of PCBs (by all routes of exposure) and conducting literature updates relevant to this assessment. The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential non-cancer health effects from PCBs by all exposure routes. All applicable Agency guidance and formats should be used in the development of this draft document.

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral RfDs and inhalation RfCs for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

The IRIS process for assessment development follows the process implemented in May 2009, including enhancements announced in July 2013 (http://www.epa.gov/iris/process.htm): a comprehensive literature search, a public problem formulation meeting, and development of a draft Toxicological Review (Step 1 of the IRIS Assessment Development Process); internal Agency review (i.e., within EPA) (Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); public review and comment and independent expert peer review (i.e., outside EPA) (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This Performance Work Statement (PWS) addresses Step 1 of the IRIS process for assessment development: development of the draft Toxicological Review. An initial draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer has been written. However, it is now necessary to update the existing draft and to develop materials (literature search strategies, evidence tables, and exposure-response figures) for release to the public for discussion at a problem formulation meeting.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2000)
- *Use of the Benchmark Dose Approach in Health Risk Assessment* (U.S. EPA, 1995)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006).

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the EPA Work Assignment Manager (WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this PWS will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, and that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall update the existing Quality Assurance Project Plan (QAPP) that was approved for EPA Contract EP-C-14-001 Work Assignment 0-15 (ICF Reference Number 130619.0.015.00, dated 02/28/2014). The Contractor shall submit the updated version to the EPA WAM and Quality Assurance Manager simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and updated QAPP are reviewed and approved.

Task 3: Literature Review

Prior to beginning work on Task 3, the Contractor shall hold a task initiation meeting with the EPA WAM to

discuss the approach, products, and expectations.

The Contractor shall screen PCB literature within EPA's HERO database to identify studies of relevance to the IRIS assessment. Determination of relevancy shall initially be based on study title and abstract or other information according to criteria developed in collaboration with the EPA WAM (see below). For each relevant study, the Contractor shall determine appropriate categories, selecting from a list to be developed by the Contractor in collaboration with the EPA WAM (see below). The Contractor shall assign tags in HERO based on the identified categories. After tagging references in EPA's HERO database, the Contractor shall generate the literature flow diagram.

Relevant literature includes studies related to health effects in animals and humans resulting from acute, subchronic, and chronic exposure durations, and from all routes of exposure. The Contractor shall identify data specifically useful for addressing risks to the general population, susceptible populations, and from exposure during particular periods of development (i.e., lifestages). Characteristics of susceptible populations might include age, sex, smoking status, pre-existing disease, genetic polymorphisms, socioeconomic status, race and ethnicity, body mass index, alcohol consumption, nutritional factors, and co-exposure to other chemical stressors. The Contractor shall include other relevant studies such as in vitro studies related to mechanism of action; studies of absorption, distribution, metabolism, and elimination; and models useful for dose-response assessment such as dosimetry, pharmacokinetic (PK), and physiologically-based pharmacokinetic (PBPK) models.

Preliminary criteria for study inclusion/exclusion and study categories will be discussed at the task initiation meeting. Within a week of this meeting, the Contractor and EPA WAM shall, in parallel, screen a test set of approximately 200 references. The Contractor shall hold a second meeting with the EPA WAM approximately one week after the task initiation meeting to discuss the results of the test set screening. These results will be used to determine study inclusion/exclusion criteria and study categories to be used by the Contractor for screening the remaining PCB literature. As work progresses on this task, the Contractor shall periodically consult with the EPA WAM to discuss the appropriate characterization of any studies for which inclusion/exclusion or appropriate study category is unclear.

Additional literature review will include elements of systematic review, including evaluation of study quality where needed. The results of any study quality analysis shall be included in the literature review product. Literature review shall be updated periodically as new literature is added to EPA's HERO database.

Task 4: Preparation of Evidence Tables

The Contractor shall provide support to EPA in preparing evidence tables that summarize organ-specific toxicity in human studies and animal bioassays. The evidence tables will be generated using the Dose Response Analytical Generator and Organizational Network (DRAGON) Tool.

Task 4a: Human Studies

Evidence tables shall be prepared for non-cancer human data identified in Task 3. The studies shall be sorted by health effect category, with separate tables for each category; studies may be in more than one table. Data from each study will be entered into the DRAGON Tool, which will then be used to generate the evidence tables. The Contractor shall initially provide the WAM with sample evidence tables for each health effect category, each populated with data from no more than 10 human studies, providing design and population details, outcome assessment details, exposure measures, and results for each study. The studies included in the sample evidence tables shall be selected to represent a variety of study designs to illustrate the proposed format for display of data from different types of studies (e.g., studies of populations exposed from different sources (occupational,

fish consumption, general population exposure), and studies using different epidemiological designs (cross-sectional, longitudinal, case-control)). The WAM will review the sample tables and provide feedback that will be used to guide the development of complete human study evidence tables (i.e., containing data from all of the relevant human studies identified in Task 3), which will also be provided to the WAM for review. As the complete tables are developed, the Contractor shall periodically consult with the EPA WAM to discuss the table entry format for study types that were not included in the sample tables or whenever the Contractor is unsure about the best format to display data for a given study. EPA will provide the Contractor with comments on the complete human study evidence tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Task 4b: Animal Studies

Concurrent with the development of evidence tables for non-cancer human exposure data in Task 4a, data from subchronic, chronic, reproductive and developmental animal toxicity studies identified in Task 3 shall be summarized in evidence tables sorted by health effect category. Separate sets of tables summarizing information from oral and inhalation exposure studies shall be prepared. Data from each study will be entered into the DRAGON Tool, which will then be used to generate the evidence tables. The Contractor shall initially provide the WAM with sample evidence tables for each health effect category, each populated with data from no more than 10 animal studies, providing study design details, outcome assessment details, exposure measures, and results for each study. The studies included in the sample evidence tables shall be selected to represent a variety of study designs to illustrate the proposed format for display of data from different types of studies (e.g., different routes of exposure (oral, inhalation, dermal), different exposure paradigms (subchronic, chronic, multigenerational)). The WAM will review the sample tables and provide feedback that will be used to guide the development of complete animal study evidence tables (i.e., containing data from all of the relevant animal studies identified in Task 3), which will also be provided to the WAM for review. As the complete tables are developed, the Contractor shall periodically consult with the EPA WAM to discuss the table entry format for study types that were not included in the sample tables or whenever the Contractor is unsure about the best format to display data for a given study. EPA will provide the Contractor with comments on the complete animal study evidence tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Task 5: Preparation of Absorption, Distribution, Metabolism, and Excretion (ADME) Inventory Tables and Synthesis Text

Prior to beginning work on Task 5, the Contractor shall hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

Task 5a: Develop Inventory Tables

Using data from studies identified in Task 3, the Contractor shall prepare tables summarizing the available evidence pertaining to absorption, distribution, metabolism, and excretion (ADME) of PCBs. Tabular presentation of pharmacokinetic (PK) and ADME data can provide the reader with a means of rapidly understanding the depth and breadth of available data. Emphasis should be placed on communicating the study design, including in vitro or in vivo, and the range of doses and time points studied. Additional information should convey the species, strain and sex of animals studied, the PCB mixture or specific congeners tested, and the time points evaluated. When available, the identification of parent compound and metabolites should be included. Finally, the conclusions supported by the available evidence should be communicated along with any notable limitations of the study.

The inventory tables for PCBs will be generated using the DRAGON Tool. The EPA WAM will provide materials (i.e., instructions and examples) to the Contractor to guide the development of the table structure for this task. The Contractor shall initially provide the WAM with sample inventory tables for each pharmacokinetic process (i.e., absorption, distribution, metabolism, and excretion), each populated with data from 3 to 5 studies. The WAM will review the sample tables and provide feedback that will be used to guide the development of complete ADME inventory tables, which will also be provided to the WAM for review. EPA will provide the Contractor with comments on the complete ADME inventory tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Task 5b: Develop Synthesis Text

The Contractor shall also develop synthesis text describing the available ADME data associated with exposure to PCBs. The synthesis section shall conform to the style and the form of the revised IRIS format. The draft synthesis shall be delivered to the EPA WAM for review. EPA will provide the Contractor with comments on the draft synthesis text. The Contractor shall address EPA comments in a revised draft and deliver the revised document to the EPA WAM. This text shall be updated as new data become available.

Task 6: Assemble Hazard Identification and/or Dose-Response Conclusions from Other Governmental or International Risk Assessment Bodies

The Contractor shall develop a table of hazard identification and/or dose-response conclusions for PCBs developed by other governmental (e.g., ATSDR, FDA) or international (e.g., IARC, WHO) risk assessment bodies. The Contractor shall research which governmental and/or international risk assessment bodies have assessments for PCBs, extract the information of interest, and summarize that information in a table. EPA will provide the table structure for this task. The Contractor shall submit the draft table to the EPA WAM for review. EPA will provide the Contractor with comments on the draft table. The Contractor shall address EPA comments in a revised version of the table and deliver the revised document to the EPA WAM.

Task 7: Preparation of Synthesis Text to Describe the Evidence for Susceptible Populations and Lifestages

Prior to beginning work on Task 7, the Contractor shall hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

Using data from studies identified in Task 3, the Contractor shall develop synthesis text summarizing the available evidence useful for addressing risks to susceptible populations and specific lifestages. Characteristics of susceptible populations might include age, sex, smoking status, pre-existing disease, genetic polymorphisms, socioeconomic status, race and ethnicity, body mass index, alcohol consumption, nutritional factors, and co-exposure to other chemical stressors. The synthesis section shall conform to the style and the form of the revised IRIS format. The draft synthesis shall be delivered to the EPA WAM for review. EPA will provide the Contractor with comments on the draft synthesis text. The Contractor shall address EPA comments in a revised draft and deliver the revised document to the EPA WAM. This text shall be updated as new data become available.

Task 8: Preparation of Inventory Tables and Synthesis Text to Describe the Evidence for Potential Modes of Action

Prior to beginning work on Task 8, the Contractor shall hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

Task 8a: Develop Inventory Tables

Using data from studies identified in Task 3, the Contractor shall prepare tables summarizing the available evidence considered for potential modes of action for PCBs. Tabular presentation of mode of action (MOA) data can provide the reader with a means of rapidly understanding the depth and breadth of available data. Emphasis should be placed on communicating the study design, including in vitro or in vivo, and the range of doses and time points studied. Additional information should convey the model system used (e.g., species, strain and sex of animals, cell line or type for in vitro studies), the assays performed, the PCB mixture or specific congeners tested, and the time points evaluated. When available, the identification of parent compound and metabolites should be included. Finally, the conclusions supported by the available evidence should be communicated along with any notable limitations of the study.

The inventory tables for PCBs will be generated using the DRAGON Tool. The Contractor shall develop the table structure for this task in collaboration with the EPA WAM, using the structure for the ADME inventory tables as a starting point and organizing studies according to MOA categories discussed at the task initiation meeting. The Contractor shall initially provide the WAM with a sample inventory table, including one or two studies for each MOA category (e.g., genotoxicity, receptor-mediated, oxidative stress). The WAM will review the sample tables and provide feedback that will be used to guide the development of complete MOA inventory tables, which will also be provided to the WAM for review. EPA will provide the Contractor with comments on the complete MOA inventory tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Task 8b: Develop Synthesis Text

The Contractor shall also develop synthesis text describing the available MOA data associated with exposure to PCBs. The text will include discussions of overarching modes of action (e.g., aryl hydrocarbon receptor activation) as well as hypotheses connecting these modes of action with the specific health effects observed with PCB exposure. The synthesis section shall conform to the style and the form of the revised IRIS format. The draft synthesis shall be delivered to the EPA WAM for review. EPA will provide the Contractor with comments on the draft synthesis text. The Contractor shall address EPA comments in a revised draft and deliver the revised document to the EPA WAM. This text shall be updated as new data become available.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word or other format, as indicated. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

TASK	DELIVERABLES
Task 1. Establish Communication	3 days after award of Work Assignment
Task 2. Work Plan, Staffing Plan, and QAPP	15 days after award
Task 3. Literature Review Products	**Task 3 initiation meeting:** 7 days after approval of the work plan and updated QAPP

TASK	DELIVERABLES
	Literature test set screening: 7 days following Task 3 initiation meeting for literature review **All studies tagged to categories in HERO and literature flow diagram completed:** 90 days following Task 3 initiation meeting for literature review Each update will be due 30 days after notification of a HERO update by EPA
Task 4a & 4b. Preparation of Evidence Tables	**Sample evidence tables for human and animal studies:** 30 days after approval of the work plan and updated QAPP **Complete evidence tables for human studies (Task 4a):** provided to the WAM as they are completed, but no later than 120 days after EPA approval of the literature review product (Task 3) and EPA providing feedback on the sample evidence tables for human studies **Revised evidence tables for human studies (Task 4a):** 30 days after receiving EPA comments on complete evidence tables for human studies **Complete evidence tables for animal studies (Task 4b):** provided to the WAM as they are completed, but no later than 120 days after EPA approval of the literature review product (Task 3) and EPA providing feedback on the sample evidence tables for animal studies **Revised evidence tables for animal studies (Task 4b):** 30 days after receiving EPA comments on complete evidence tables for animal studies **Updates for Tasks 4a & 4b:** 30 days after notification of a HERO update by EPA
Task 5a & 5b. Preparation of Absorption, Distribution, Metabolism, and Excretion (ADME) Inventory Tables and Synthesis Text	**Task 5 initiation meeting:** 60 days after approval of the work plan and updated QAPP **Sample inventory tables for ADME studies:** 30 days following Task 5 initiation meeting **Complete ADME inventory tables (Task 5a):** 90 days after receiving EPA comments on sample inventory tables **Revised ADME inventory tables (Task 5a):** 30 days after receiving EPA comments on complete ADME inventory tables

TASK	DELIVERABLES
	Draft synthesis text (Task 5b): 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 5b):** 30 days after receiving EPA comments on draft synthesis text **Updates for Tasks 5a & 5b:** 30 days after notification of a HERO update by EPA
Task 6. Assemble Hazard Identification and/or Dose-Response Conclusions from Other Governmental or International Risk Assessment Bodies	**Draft table:** 30 days after approval of the work plan and updated QAPP **Revised table:** 30 days after receiving EPA comments on draft table
Task 7. Preparation of Synthesis Text to Describe the Evidence for Susceptible Populations and Lifestages	**Task 7 initiation meeting:** 60 days after approval of the work plan and updated QAPP **Draft synthesis text:** 90 days following Task 7 initiation meeting **Revised synthesis text:** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 8a & 8b. Preparation of Inventory Tables and Synthesis Text to Describe the Evidence for Potential Modes of Action	**Task 8 initiation meeting:** 90 days after approval of the work plan and updated QAPP **Sample inventory tables for MOA studies:** 30 days following Task 8 initiation meeting **Complete MOA inventory tables (Task 8a):** 90 days after receiving EPA comments on sample inventory tables **Revised MOA inventory tables (Task 8a):** 30 days after receiving EPA comments on complete MOA inventory tables **Draft synthesis text (Task 8b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 8b):** 30 days after receiving EPA comments on draft synthesis text **Updates for Tasks 8a & 8b:** 30 days after notification of a HERO update by EPA

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

X. Work Assignment Manager (WAM)

Geniece M. Lehmann, Ph.D.
Telephone: 919-541-2289
Fax: 919-541-0245
e-mail: Lehmann.Geniece@epa.gov

USPS Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

Alternate Work Assignment Manager:

Jeff Gift, Ph.D.
Telephone: 919-541-4828
Fax: 919-541-0245
e-mail: Gift.Jeff@epa.gov

USPS Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-15

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	EVIDENCE TABLES
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 05/13/2015 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$365,632.00	3,982
Total:	$365,632.00	3,982

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 06/11/2015	$365,632.00	3,982
Cumulative Approved:	$365,632.00	3,982

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2289 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-17

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Product Development
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A1. Human Health Assessment Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/03/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Taukecha Cunningham (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0294 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-17

TITLE: Scientific and Technical Product Development for NCEA

Specify Section & Paragraph SOW: **A1. Human Health Assessment Documents**

PERIOD of PERFORMANCE: CO approval through October 31, 2015

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 0-17. The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) for document production activities which include technical editing, word processing, and graphics support.

II. BACKGROUND

The National Center for Environmental Assessment (NCEA), a major component of EPA's Office of Research and Development (ORD), with headquarters in Washington, DC, is EPA's national resource center for human health and ecological risk assessment. NCEA occupies a critical position in ORD between researchers in other parts of ORD and outside of EPA who are generating new findings and data, and the regulators in EPA's program offices and regions who must make regulatory, enforcement, and remedial action decisions. NCEA prepares technical reports and assessments that integrate and evaluate the most up-to-date research and serve as major elements of the science foundation supporting EPA policies. As a result, NCEA plays an important role as a consultant to EPA programs and regions on the use of science in environmental decision making and also influences the direction of environmental research.

III. STATEMENT OF WORK

The purpose of this work assignment is to provide technical editing and/or revisions of approximately 6 documents. For the purpose of developing the cost for the work plan, the contractor can assume that each document is approximately 150 pages.

Task 1: Establish Communication

Within 3 days of the start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The WAM will submit the documents to be edited via a Contract Service Form. This form will be used as instructions to the contractor and will be submitted with each document. Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel.

Technical/Nontechnical Writing and Technical Editing

The contractor shall ensure the quality of NCEA products by providing technical writing and editorial services for ORD special reports, technical documents, and other written materials. The contractor shall use the Editing Guidelines/Procedures specified by the WAM (*Handbook for Preparing NCEA Documents,* IRIS template, or other specific guidelines, e.g., journal manuscripts would have their own format).

The contractor shall provide an editor (scientist) with an excellent command of the English language, grammar, and spelling. The editor shall be experienced in scientific and technical writing.

The contractor shall perform various tasks in support of EPA research and development efforts including the following:

• Write or rewrite scientific/technical material for scientific and technical audiences. The original document or manuscript provided generally will have been written by specialists in the subject. The contractor must be familiar with scientific and technical terminology (e.g., risk assessment, ecology, solid and hazardous waste, incineration and combustion, etc.) and shall revise the document to the point that it can be easily read and comprehended by the technical community.

• Write or rewrite scientific/technical material in terminology familiar to educated laymen. Rewriting shall include assessing previously written material for unity, coherence, and appropriateness of language and style for the intended audience.

• The contractor shall edit documents electronically using the track edit feature or perform a hard copy edit (legible, handwritten corrections in red ink on the hard copy of the document) when requested.

• The contractor shall closely read the manuscript to ensure correct grammar, spelling, and punctuation; consistency of capitalization, spelling, and hyphenation; agreement of verbs and subjects; check materials, especially tables, figures, units of measure, headings, etc. for consistency of style and format; check placement of tables and figures; and many other details of style.

• The contractor shall rewrite or reorganize sentences, paragraphs, sections, etc.; verify the accuracy of technical terminology, assess illustrations to determine clarity of presentation, need for redrawing, retouching, etc.; cross-check information in the text to tables, figures, appendices, and references and correct apparent disagreements; correct inconsistencies in format and style; assure consistency and accuracy of chemical formulae, mathematical expressions, tables, figures, equations, chemical and biological names; provide a list of queries regarding any questions or concerns with reference to their location in the document; rewrite as needed to ensure clarity throughout the document and that tone and complexity of the document are appropriate for the intended audience.

• The contractor shall check references to ensure that all references cited in the text and only those references have been included in the reference section of the document and verify the accuracy, completeness, and adherence to established format. The contractor will add links for references that are in the HERO library.

• The contractor must be conscientious, attentive to detail, and able to work under considerable pressure (e.g., ability to manage multiple projects that have very short deadlines).

Word Processing/Graphics

The material provided to the contractor shall be provided in a variety of formats including, but not limited to, handwritten form or typed rough draft. Documents may contain chemical formulae, mathematical expressions, tables, figures, equations, chemical and biological names, and other terminology specific to scientific/technical documents. The contractor shall operate IBM-compatible PCs and associated peripheral devices (printers, scanners) and provide support for software applications such as Microsoft Office Suite, Word Perfect, or other applications introduced as EPA standard.

- The contractor shall become familiar with NCEA formatting standards and make any necessary revisions and/or formatting corrections to documents. The contractor shall use features of MS Word as needed (e.g., indexing, generated Table of Contents, text art, etc.).

- The contractor shall plan layout and typing of complicated statistical tables and equations to maintain uniformity and balance in spacing (equations will be typed using the current version of MS Word's Equation Editor). The contractor must be conscientious and attentive to detail.

- The contractor must have excellent proofreading skills.

All word processed material shall be proofread. The contractor shall compare corrections made by the word processor with those requested by the author for accuracy and return the document for further correction as needed.

- Using standard graphics software (e.g., Illustrator, InDesign), the contractor shall create or revise figures as needed.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, InDesign).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of WA
Task 2. Work Plan and Staffing Plan	20 days after award

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the WAM at the initiation of the work assignment. Standard reporting requirements of the contract apply for active/completed projects.

IX. OTHER REQUIREMENTS

The WAM will have oversight on all materials developed by the contractor. The primary communication mechanism between the WAM and the contractor shall be email.

In cases where the work to be performed is of a highly scientific or technical nature or requires consultation or interactions, it may be more expedient for the contractor to interact directly with members of the scientific/technical staff.

X. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this WA shall be sent to the PO.

Work Assignment Manager:

Taukecha Cunningham
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: 703-347-0294; Fax: 703: 703-347-8691
Cunningham.taukecha@epa.gov

Physical Address:
Two Potomac Yard (North Building) N-7341
2733 S. Crystal Drive,
Arlington, VA 22202

Alternate Work Assignment Manager:

Terri Konoza
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: 703-347-8672; Fax: 703-347-8691
konoza.terri@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-17

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Product Development
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A1. Human Health Assessment Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/03/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$70,043.00	590
Total:	$70,043.00	590

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/21/2014	$70,043.00	590
Cumulative Approved:	$70,043.00	590

Work Assignment Manager Name: Taukecha Cunningham (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0294 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-18

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	Draft Development of the Toxic

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW: Assessment Issues and Documents 1. Human Health As

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Janice S. Lee (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9458 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-18

TITLE: Draft Development of the Toxicological Review of Inorganic Arsenic (cancer and non-cancer effects)

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: *11/1/2014 - 10/31/2015*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for development of a human health risk assessment for toxicological effects of oral exposure to inorganic arsenic (iAs). The development of the iAs human health risk assessment will include the draft development of evidence tables and draft development of a human health risk assessment of both cancer and non-cancer effects of oral exposure to iAs, including potential use of probabilistic risk assessment methodology.

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides human health toxicity values for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

The IRIS process for assessment development follows the process implemented in May 2009 (http://www.epa.gov /iris/process.htm), which consists of: a comprehensive literature search; a call for technical information from the public via a Federal Register notice; development of a draft Toxicological Review (Step 1 of the IRIS Assessment Development Process); internal Agency review (i.e., within EPA) (Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); external peer review (i.e., outside EPA) and public review and comment (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This PWS addresses Step 3 of the IRIS process for assessment development: development of the draft Toxicological Review. The overall goal of the iAs human health risk assessment is to provide scientifically-defensible reasoning for the choice of critical cancer and non-cancer effects due to oral exposure of iAs exposure, along with the literature and principal study(ies) that best represent and support that choice.

The Contractor shall extract data and develop evidence tables for the major toxicological effects for the draft Toxicological Review. EPA will identify the studies to be included in these tables as well as provide the table structure for this task. The Contractor shall also help draft sections of the iAs human health risk assessment. The Contractor shall manage the drafting process, including identifying and selecting expert writers as well as managing the drafting process. The Contractor shall also provide options for the probabilistic risk assessment of effects resulting from iAs exposure. The Work Assignment Manager (WAM) and other EPA internal reviewers will provide technical direction as necessary.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006)

III. STATEMENT OF WORK

A. Objective

The objective of this Work Assignment (WA) is to provide technical support for the development of the Toxicological Review of Inorganic Arsenic (cancer and non-cancer effects). Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

B. Specific Requirements

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA Work Assignment Manager (WAM).

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; and "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data.*"

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Efforts related to Source Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in responding to reviewer comments on source considerations for inorganic arsenic, including revisions to the source characterization summary report. All applicable Agency guidance and formats should be used in preparing response to reviewer comments. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

3.1 Source Characterization – Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised versions of source characterization documents based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions to the source characterization summary report(s) and written responses to comments, as necessary.

Deliverables:
Revised source characterization summary report
Written responses to comments on source characterization (based upon technical direction)

Task 4: Efforts related to Stressor Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in responding to reviewer comments on stressor considerations for inorganic arsenic. All applicable Agency guidance and formats should be used in preparing response to reviewer comments. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

4.1 Stressor Considerations – Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to stressor considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents related to stressor considerations
Written responses to comment on documents related to stressor considerations (based upon technical direction)

Task 5: Efforts related to Exposure Pathway Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in in responding to reviewer comments on exposure pathway considerations for inorganic arsenic, which may include revising exposure pathway models. All applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

5.1 Exposure Pathway Model Considerations – Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to exposure pathway considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/models related to exposure pathway considerations
Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

Task 6: Efforts related to Receptor Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in developing an IRIS toxicological review for inorganic arsenic. The toxicological review shall characterize potential receptors of inorganic arsenic exposure. Receptors are populations, including life stages, which are exposed to the stressor. Potential human receptors include the general population, susceptible populations (e.g., pre-existing diseases, smoking, drinking, lifestages, etc.), and exposure during particular periods of development. This document will implement recommendations made by National Research Council in "Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic – Interim Report" with respect to consideration of sources of exposure. In addition, all applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

6.1 Receptor Considerations - Sensitivity analyses: The Contractor shall develop sensitivity analyses to determine how receptor considerations impact dose-response analyses for inorganic

arsenic. Receptor considerations for sensitivity analyses shall include, but are not limited to, smoking synergism size effect for health effects associated with inorganic arsenic. Data required to perform sensitivity analyses shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database.

Deliverable:
Sensitivity analyses describing the impact of receptor considerations on dose-response analyses

6.2 Receptor Considerations - Analyses of health effects associated with inorganic arsenic exposure from drinking water in the United States: The Contractor shall develop analyses examining the potential associations between drinking water exposure and health effect endpoints in the United States. Endpoints may include, but are not limited to, mortality, bladder cancer, cardiovascular disease, and diabetes. Data required to perform these analyses shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database.

Deliverable:
Analyses of potential association between drinking water arsenic exposure and health effect endpoints in the United States

6.3 Receptor Considerations - Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to receptor considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/analyses related to receptor considerations
Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

Task 7: Efforts related to Endpoint Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in developing an IRIS toxicological review for inorganic arsenic. The toxicological review shall characterize potential endpoints of inorganic arsenic exposure. Endpoints are measures of the effects of exposure to inorganic arsenic. Potential endpoints associated with exposure to inorganic arsenic include both cancer and non-cancer health effects. Consideration of health effects in the IRIS toxicological review of inorganic arsenic will implement recommendations made by National Research Council in "Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic – Interim Report" with respect to. In addition, all applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

7.1 Endpoint Synthesis Text: The Contractor shall identify, recruit and manage expert scientists to author synthesis sections. The synthesis sections shall evaluate the available data on endpoints associated with exposure to inorganic arsenic, including data presented in endpoint evidence tables. Where possible, the Contractor shall develop meta-analyses for endpoints as

recommended by the National Research Council. These meta-analyses shall be reviewed by the identified experts as part of developing the synthesis sections. The synthesis sections shall conform to the style and the form of the revised IRIS format, generally. The Contractor shall be responsible for ensuring necessary communication from the EPA reaches the expert authors so that technical clarification can be offered and interaction between authors can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

The EPA assumes primary authorship in the writing process and contributing authors are listed in the final document as appropriate. The expert writers will receive authorship credit on the IRIS Toxicological Review of Inorganic Arsenic and therefore will be considered responsible for the scientific content. EPA will review the qualifications of the expert authors performing this work within two days of notification of a potential candidate to ensure the potential candidates meet the criteria to perform this task. Specific responsibilities for this sub-task include:

7.1.1 Manage the drafting process and public webinar- The Contractor shall manage the expert scientists recruited to author sections of the Toxicological Review and ensure communication between EPA and the expert authors. This shall involve setting up approximately 4 conference calls with authors and EPA staff.

Expert authors have two primary responsibilities for developing these synthesis sections: prepare a final draft of the synthesis section and present the hazard identification materials in a public meeting or webinar. Expert authors will develop hazard identification synthesis section for health effects. EPA will provide an initial draft of the synthesis section, including draft text and evidence tables, as well as access to literature on the HERO database. The expert author should make necessary revisions to the initial draft and submit a revised draft for EPA review.

After completing a revised draft, the expert author will present the hazard identification materials in a public webinar. The expert writer will be responsible for revising the draft to incorporate comments or suggestions from these webinar prior to submitting a final draft for EPA review.

In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this statement of work.

Deliverables:
Establishing communication between EPA and expert writers (minimum 4 conference calls)
Endpoint synthesis section, including where possible meta-analyses, delivered by deadlines noted in SOW
Webinar on endpoint synthesis section

7.2 Endpoint Qualitative Mode of Action Syntheses: The Contractor shall assist EPA in developing qualitative mode of action syntheses. These syntheses will evaluate the available mechanistic data for several potential modes of action of inorganic arsenic. Potential modes of action may

include, but are not limited to, apoptosis and cellular proliferation, activation of reactive oxygen species, impaired immune function, and changes in gene expression and/or regulation. The mode of action syntheses will inform the endpoint causal determination.

7.2.1. Endpoint Qualitative Mode of Action Syntheses Summary Tables: The Contractor shall prepare tables summarizing the available evidence considered during qualitative evaluation of potential modes of action for inorganic arsenic. At a minimum, these tables should include the relevant bibliographic information, description of study design/quality, reported effects of iAs exposure, and dose-response information. These tables shall be updated as new data become available. The data used to create these evidence tables shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database.

Deliverable:
Summary tables on potential modes of action, including updates to incorporate new data

7.2.2. Endpoint Qualitative Mode of Action Synthesis: The Contractor shall develop synthesis text qualitatively describing potential modes of action for inorganic arsenic. The synthesis sections shall evaluate the available mechanistic data on inorganic arsenic associated with exposure to inorganic arsenic, including data presented in endpoint qualitative mode of action summary tables. The synthesis sections shall conform to the style and the form of the revised IRIS format, generally. The Contractor shall be responsible for ensuring communication between the EPA and the expert authors so that technical clarification can be offered and interaction between authors can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

Deliverable:
Endpoint Qualitative Mode of Action syntheses delivered by deadlines noted in SOW

7.2.3. Evaluation of Microarray Data: The Contractor shall prepare tables summarizing the available evidence using microarray data to investigate. The contractor shall evaluate the available studies using microarray data using the Systematic Omics Analysis Review (SOAR). The SOAR evaluation shall be used as guidance for determining if the data are appropriate for consideration in the assessment. At a minimum, these tables should include the relevant bibliographic information, description of study design/quality, SOAR scores, and dose-response information. These tables shall be updated as new data become available. The data used to create these evidence tables shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database. For considered microarray data, the Contractor shall perform pathway analyses and organize the available studies by potential modes of action.

Deliverables:
Summary tables of microarray studies
Pathway analysis for microarray data organized by modes of action

7.3 Endpoint – Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to endpoint considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/analyses related to endpoint considerations
Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

Task 8: Efforts related to Risk Metric Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in developing an IRIS toxicological review for inorganic arsenic. The toxicological review shall characterize risk metrics of inorganic arsenic exposure. Risk metrics are measures by which effects of inorganic arsenic exposure are quantified. Quantification of health effects in the IRIS toxicological review of inorganic arsenic will implement recommendations made by National Research Council in "Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic – Interim Report" with respect to. In addition, all applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

8.1 Risk Metric Dose-Response Analyses: The Contractor shall assist EPA in performing meta-analyses and dose-response analyses, in accordance with technical direction. The Contractor shall use materials developed by the EPA to perform requested dose-response analyses. The Contractor duties may include, but are not limited to, extracting data for dose-response analyses, performing dose-response analyses, and developing tables summarizing the results of dose-response analyses. The data used to perform dose-response analyses tables shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database.

Deliverable:
Meta-analyses and dose-response analyses, as per technical direction

8.2 Risk Metric Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents or analyses related to risk metric considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/analyses related to risk metric considerations
Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award
Task 3. Efforts related to Source Considerations for Inorganic Arsenic	
Task 3.1 - Source Characterization – Response to Reviewer Comments	
• Revised source characterization summary report	3 weeks from receipt of reviewer comments
• Written responses to comments on source characterization (based upon technical direction)	3 weeks from receipt of reviewer comments
Task 4. Efforts related to Stressor Considerations for Inorganic Arsenic	
Task 4.1 – Stressor Considerations – Response to Reviewer Comments	
• Revised documents related to stressor considerations	2 weeks from receipt of reviewer comments
• Written responses to comment on documents related to stressor considerations (based upon technical direction)	2 weeks from receipt of reviewer comments
Task 5. Efforts related to Exposure Pathway Considerations for Inorganic Arsenic	
Task 5.1 - Exposure Pathway Model Considerations – Response to Reviewer Comments	
• Revised documents/models related to exposure pathway considerations	6 weeks from receipt of reviewer comments
• Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)	6 weeks from receipt of reviewer comments
Task 6. Efforts related to Receptor Considerations for Inorganic Arsenic	
Task 6.1 – Receptor Considerations - Sensitivity analysis	
• Sensitivity analyses describing the impact of receptor considerations on dose-response analyses	3 months from award of Work Assignment
Task 6.2 - Analyses of health effects associated with inorganic arsenic exposure from drinking water in the United States	
• Analyses of potential association between drinking water arsenic exposure and health effect endpoints in the United States	4 months from award of Work Assignment
Task 6.3 - Receptor Considerations – Response to Reviewer Comments	
• Revised documents/models related to exposure pathway considerations	4 weeks from receipt of reviewer comments
• Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)	4 weeks from receipt of reviewer comments

Task 7. Efforts related to Endpoint Considerations for Inorganic Arsenic	
Task 7.1 - Endpoint Synthesis Text	
Task 7.1.1 - Manage the drafting process and public webinar	
• Establishing communication between EPA and expert writers (minimum 4 conference calls)	3 months from award of Work Assignment
• Endpoint synthesis section, including meta-analyses where possible	3 months from award of Work Assignment
• Webinar on endpoint synthesis section	3 months from receipt of draft endpoint synthesis from EPA
Task 7.2 - Endpoint Qualitative Mode of Action Syntheses	
Task 7.2.1 - Endpoint Qualitative Mode of Action Syntheses Summary Tables	
• Summary tables on potential modes of action, including updates to incorporate new data	2 months from award of Work Assignment (updates as needed)
Task 7.2.2 - Endpoint Qualitative Mode of Action Synthesis	
• Endpoint Qualitative Mode of Action syntheses	6 weeks from award of Work Assignment
Task 7.2.3 - Evaluation of Microarray Data	
• Summary tables of microarray studies	2 months from award of Work Assignment
• Pathway analysis for microarray data organized by modes of action	5 months from award of Work Assignment
Task 7.3 - Endpoint Considerations – Response to Reviewer Comments	
• Revised documents/models related to endpoint considerations	5 weeks from receipt of reviewer comments
• Written responses to comment on documents related to endpoint considerations (based upon technical direction)	5 weeks from receipt of reviewer comments

Task 8. Efforts related to Risk Metric Considerations for Inorganic Arsenic	
Task 8.1 -Risk Metric Dose-Response Analyses	
• Meta-analyses and dose -response analyses, as per technical direction	4 months from award of Work Assignment
Task 8.2 – Risk Metric Considerations – Response to Reviewer Comments	
• Revised documents/models related to exposure pathway considerations	8 weeks from receipt of reviewer comments
• Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)	8 weeks from receipt of reviewer comments

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Managers (WAMs):

Janice S. Lee, PhD
919-541-9458
Lee.JaniceS@epamail.epa.gov

John Cowden, PhD
919-541-3667
Cowden.John@epamail.epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-18

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	Draft Development of the Toxic

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A. Assessment Issued & Docs

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:
This amendment corrects the PWS by confirming that Task 7 is an optional task and was for pricing purposes only. The contractor shall not commence any work on task 7 unless and until notified, in writing, by the WA-COR.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Janice S. Lee (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9458 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-18 Amend 1

TITLE: Draft Development of the Toxicological Review of Inorganic Arsenic (cancer and non-cancer effects)

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: *11/1/2014 - 10/31/2015*

III. STATEMENT OF WORK

Optional Task 7.1.2- this task was included and was to be optional and for pricing purposes only. The contractor shall not commence any work to optional task 7 unless or until notified, in written technical direction, to begin optional work on task 7.

Task 7: Efforts related to Endpoint Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in developing an IRIS toxicological review for inorganic arsenic. The toxicological review shall characterize potential endpoints of inorganic arsenic exposure. Endpoints are measures of the effects of exposure to inorganic arsenic. Potential endpoints associated with exposure to inorganic arsenic include both cancer and non-cancer health effects. Consideration of health effects in the IRIS toxicological review of inorganic arsenic will implement recommendations made by National Research Council in "Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic – Interim Report" with respect to. In addition, all applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

7.1 Endpoint Synthesis Text: The Contractor shall identify, recruit and manage expert scientists to author synthesis sections. The synthesis sections shall evaluate the available data on endpoints associated with exposure to inorganic arsenic, including data presented in endpoint evidence tables. Where possible, the Contractor shall develop meta-analyses for endpoints as recommended by the National Research Council. These meta-analyses shall be reviewed by the identified experts as part of developing the synthesis sections. The synthesis sections shall conform to the style and the form of the revised IRIS format, generally. The Contractor shall be responsible for ensuring necessary communication from the EPA reaches the expert authors so that technical clarification can be offered and interaction between authors can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

The EPA assumes primary authorship in the writing process and contributing authors are listed in the final document as appropriate. The expert writers will receive authorship credit on the IRIS Toxicological Review of Inorganic Arsenic and therefore will be considered responsible for the scientific content. EPA will review the qualifications of the expert authors performing this work within two days of notification of a potential candidate to ensure the potential candidates meet the criteria to perform this task. Specific responsibilities for this sub-task include:

7.1.1 Manage the drafting process and public webinar- The Contractor shall manage the expert scientists recruited to author sections of the Toxicological Review and ensure communication between EPA and the expert authors. This shall involve setting up approximately 4 conference calls with authors and EPA staff.

Expert authors have two primary responsibilities for developing these synthesis sections: prepare a final draft of the synthesis section and participate in a public meeting or webinar (see optional task 7.1.2). Expert authors will develop hazard identification synthesis section for health effects. EPA will provide an initial draft of the synthesis section, including draft text and evidence tables, as well as access to literature on the HERO database. The expert author should make necessary revisions to the initial draft and submit a revised draft for EPA review.

Optional 7.1.2.

After completing a revised draft, the expert author will participate in a public webinar where the hazard identification materials will be presented. If webinars will occur, written technical direction will be provided to the Contractor. Work on webinars are not to begin until receipt of technical direction. The expert writer will be responsible for revising the draft to incorporate comments or suggestions from these webinars prior to submitting a final draft for EPA review.

In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this statement of work.

Deliverables:
Establishing communication between EPA and expert writers (minimum 4 conference calls)
Endpoint synthesis section, including where possible meta-analyses, delivered by deadlines noted in SOW
Optional Deliverable:
Webinar on endpoint synthesis section

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-18

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Draft Development of Toxic
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: Assessment Issues and Documents 1. Human Health As

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$617,252.00	5,270
Total:	$617,252.00	5,270

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 02/17/2015	$617,252.00	5,270
Cumulative Approved:	$617,252.00	5,270

Work Assignment Manager Name: Janice S. Lee	(Signature)	(Date)	Branch/Mail Code: Phone Number: 919-541-9458 FAX Number:
Project Officer Name: Melissa Revely-Wilson	(Signature)	(Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: Melissa Revely-Wilson	(Signature)	(Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Contracting Official Name: Adam Meier	(Signature)	(Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-18

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	As Tox Review

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$594,127.00	5110
This Action:	$491,659.00	4,708
Total:	$1,085,786.00	9,818

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 06/11/2015	$491,659.00	4,708
Cumulative Approved:	$1,085,786.00	9,818

Work Assignment Manager Name: Janice S. Lee (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9458 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-19

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Hexavalent Chromium
	Base Option Period Number 1	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

1. Human Health Assessment Documents
B. Risk Assessment Data Bases and Computer Tools exposure assessment
D. Analysis, Document and Issue Paper Preparation
E. Risk Assessment Support

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Catherine Gibbons (Signature) (Date)	Branch/Mail Code: Phone Number: 703-603-0704 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-19

TITLE: Preparation and Revision of the IRIS Draft Toxicological Review of Hexavalent Chromium (CAS No. 18540-29-9)

Specify Section & Paragraph SOW:

A. Assessment Issues and Documents
1. Human Health Assessment Documents
B. Risk Assessment Data Bases and Computer Tools exposure assessment
D. Analysis, Document and Issue Paper Preparation
E. Risk Assessment Support
G. Literature Search

PERIOD OF PERFORMANCE: *11/1/14 to 10/31/15*

I. PURPOSE

This work assignment is a continuation of work performed in the Base Period under Work Assignment #0-19. The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD) related to the development of the Toxicological Review of Hexavalent Chromium. Specifically, support may include developing Sections 1 and 2 of a draft Toxicological Review on the potential health hazards of hexavalent chromium (by all routes of exposure) and the Integrated Risk Information System (IRIS) Summary for this chemical, providing support in addressing comments on the draft Toxicological Review following formal review steps, conducting literature updates relevant to this assessment, and performing technical edits. The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential health effects from hexavalent chromium by all exposure routes. This document shall include derivation of an oral reference dose (RfD), inhalation reference concentration (RfC), oral slope factor, and inhalation unit risk where scientifically feasible and provide justification for those instances where quantitative derivations are deemed infeasible or not necessary. This document shall also present information used to assign the cancer weight-of-evidence descriptor for hexavalent chromium. All applicable Agency guidance and formats should be used in the development of this draft document.

II. BACKGROUND

EPA's IRIS Program is an assessment program that evaluates qualitative and quantitative information on human health effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides science-based human health assessments to support the Agency's activities. The IRIS database contains hazard characterization and toxicity values for the first two steps of the risk assessment process—hazard identification and dose-response assessment. By combining IRIS toxicity values with information on chemical exposure, government and other entities can characterize health risks of chemicals.

EPA's process for developing IRIS assessments consists of: (1) draft development, which includes a public meeting focused on identifying the available scientific information; a comprehensive search of the scientific literature; release of preliminary materials (literature search and associated search strategies, evidence tables, and exposure-response figures); and a public meeting to discuss the early materials; (2) EPA-wide internal review; (3) science consultation on the draft assessment with other Federal agencies and the Executive Office of the President; (4) public review and comment, including a public meeting to discuss the draft assessment and draft peer review charge, and independent expert peer review; (5) revision of the assessment to address peer review and public

comments; (6) a second EPA-wide internal review and interagency discussion with other Federal agencies and the Executive Office of the President; and (7) posting of the final assessment to the IRIS website (www.epa.gov/iris/).

A Toxicological Review of Hexavalent Chromium, which assessed the health effects of both oral and inhalation exposures to hexavalent chromium, was posted to the IRIS database in 1998. A reassessment of hexavalent chromium was initiated in 2008 in light of new scientific information, with the oral assessment expedited due to EPA program office needs. This draft of the reassessment of the noncancer and cancer health effects associated with oral exposure to hexavalent chromium was produced on a separate track and was submitted for public comments and external peer review (see http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=221433). A draft of the Toxicological Review of Hexavalent Chromium by inhalation (and other non-oral) exposures was later initiated as a separate document from the draft Toxicological Review for oral exposures. However, it is now appropriate to combine and revise these documents into one draft Toxicological Review of Hexavalent Chromium by all routes of exposure. The existing draft assessments will be reorganized consistent with a modified Toxicological Review template that has been produced in response to comments provided by the National Academies of Science in their external expert review of the Toxicological Review of Formaldehyde. In addition, the Toxicological Review will be updated to included relevant literature identified in an updated comprehensive literature search of the health effects of hexavalent chromium by all exposures.

This PWS addresses the following steps of the IRIS process for assessment development: Step 3—development of the draft Toxicological Review; Steps 2, 3, 4, 5, and 6—revision of the assessment in response to comments; and Step 5—preparation of an IRIS Summary.

In developing the Toxicological Review and IRIS Summary, the Contractor shall follow applicable EPA guidance (see http://www.epa.gov/iris/backgrd.html).

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, statistics, and library science. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data*"; "*EPA 100/B-03/001: A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (2003)," and the addendum, "*Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information* (2012)."

The QAPP shall be submitted simultaneously with the Work Plan for approval.

Task 3: Update and Quality Assurance of Evidence Tables

The Contractor shall provide support to EPA in performing updates and quality assurance checks of tables that summarize organ-specific toxicity in human studies and animal bioassays (i.e., evidence tables) as well as tables presenting summaries of ADME (absorption, distribution, metabolism, and excretion) and genetic toxicity studies. Updates of evidence tables shall be performed to add new studies identified through literature search updates performed during development of the draft assessment or during review steps. Quality assurance checks shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), confirming effect levels, and inserting and verifying HERO links. For each health effect category, separate evidence tables will be developed (if data are available); only inhalation and oral routes of exposure will be considered. The quality assurance check should be performed by a scientist that was not involved in the initial development of the table being reviewed. These tables will be provided to the Contractor by the WAM.

Task 4: Technical Editing of the Draft Toxicological Review of Hexavalent Chromium and IRIS Summary

The Contractor shall conduct technical edits of the Toxicological Review prior to release for public comment/external peer review and prior to posting on the IRIS web site. The Contractor shall also conduct a technical edit of the IRIS Summary prior to posting.

Technical editing, which involves the reworking of written technical material for a specialized audience, may include: arranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc.; standardizing symbols; verifying and restyling reference citations where required; and cross-checking information in text, tables, and figures, as well as correcting errors in grammar, spelling, and punctuation. This work shall be performed according to EPA guidance related to the technical editing; the Handbook for Preparing NCEA Documents shall be used as a primary reference to resolve issues involving usage and style. All products will be formatted using current versions of IRIS Summary and Toxicological Review templates. The reference list shall be formatted according to the output in HERO (i.e., the HERO format supersedes the Handbook for Preparing EPA Documents). Technical editing includes:

a. Mechanical editing – Close reading of the manuscript to ensure correct grammar, spelling, syllabification, and punctuation; consistency of capitalization, spelling, and hyphenation; agreement of verbs and subjects; agreement of pronouns; correct use of adverbs and adjectives; beginning and ending quotation marks and parentheses; correct use of ellipsis; cross-checking contents with text to verify accuracy and consistency of headings, subheadings, and page numbers; and many other details of style.

b. Substantive editing – Involves any or all of the following: arranging or rearranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc; standardizing symbols; verifying and restyling reference citations; cross-checking information in the text to tables, figures, appendices, and references and correct apparent disagreements; correcting inconsistencies in format and style.

c. Checking references to ensure that all references cited in the text and only those references have been included in the reference section of the document and verifying accuracy, completeness, and adherence to established format. In the event that information is missing, consulting authors or procuring copies of cited material to complete reference.

d. HERO links – HERO links shall be added to any text in which links were not included.

The Contractor shall provide a final electronic mark-up (in 'Track Changes' format of Microsoft Word) of the draft Toxicological Review of Hexavalent Chromium and the IRIS Summary to the WAM no more than 20 days after receipt of the draft document from the WAM.

Task 5: Updates to Literature Search

The Contractor shall perform literature search updates during the review processes at regularly scheduled intervals during assessment development (i.e., through release for external peer review) and at least once after external peer review. The interval (i.e., number of months) between literature search updates shall be determined in consultation with the Contractor. The literature search strategy shall be consistent with the strategy for the initial hexavalent chromium literature search conducted by ICF and with the latest draft of the Handbook for IRIS Assessment Development. The Contractor shall add new references to HERO, tag references consistent with existing tags in HERO, and document the updated literature search strategy and findings.

If questions arise during the literature search and screening task (e.g., difficulties in narrowing down the number of "hits" from the search, questions about the relevance of certain types of papers or topics, retrieval of difficult to obtain documents or foreign language papers), the Contractor shall contact the WAM for further consultation.

Task 6: Maintenance of the HERO Database for Hexavalent Chromium Literature

The Contractor shall perform the following to ensure the HERO database is up to date with the most current Toxicological Review of Hexavalent Chromium:

- Combine HERO litbrowser folders for "Chromium VI (oral)" and "Chromium VI (other)"
- Ensure that all literature referenced in the IRIS document can be found in HERO
- Ensure that references listed in HERO for a "chromium" search but are not referenced in the IRIS document do not contain tags that suggest otherwise
- Ensure that references are appropriately tagged, both in their HERO listings and in the hyperlinks embedded in the document
- Ensure that retrieved pdfs of references in the IRIS document are uploaded to HERO

OPTIONAL TASKS

The following tasks are optional. If EPA determines the services under these tasks are required, the EPA WAM will initiate by issuing written technical direction. These optional tasks should be addressed in the technical proposal and included in the cost proposal of the work plan.

Optional Task 7: Synthesis of the Evidence for Selected Health Effects

Upon completion of Task 3, the Contractor shall develop a synthesis of the available evidence for selected health effect categories for which evidence tables have been generated, The Contractor shall refer to the latest draft of the Handbook for IRIS Assessment Development for guidance in developing this synthesis text (see section entitled "Evaluating the Overall Evidence of Each Effect"). Health effects information for effects with limited literature can be included in a section titled "Other Toxicological Effects." The text should reflect a synthesis of the overall findings for each health effect rather than a summary of individual studies.

The Contractor shall submit the draft syntheses to the WAM for review as they are completed. Based on comments from the WAM, the Contractor shall submit a final synthesis for each health effect section (except human inhalation exposure).

Optional Task 8: Support in Addressing Comments on the Toxicological Review following Various Review Steps

The Contractor shall provide support to the EPA in addressing comments received during various review steps, including Agency review, interagency review, external peer review, and public comment. EPA cannot anticipate the number or nature of comments that will be received at each review step or the specific type of Contractor support that will be required following any given review step. EPA estimates that support will consist of the following tasks: summarize comments by topic or issue, research special topics or issues that may be raised in comments, conduct additional BMD or other modeling/analysis as appropriate, revise the Toxicological Review in response to comments, and assist in developing written responses to comments. The Contractor may also be asked to populate Comment-Tracker, an Access database developed by EPA to manage comments (and responses) on the draft assessment. The Contractor may also be asked to attend the interagency review meeting (via teleconference) and take notes during that meeting for internal use. All of these tasks will require a quick turn-around time.

Optional Task 9: Preparation of IRIS Summary

Prior to final Agency review and interagency science discussion, the Contractor shall prepare the IRIS Summary. The IRIS Summary shall be developed using the latest IRIS Summary template (to be provided by the WAM) and instructions for IRIS Summary development in the SOPs. The IRIS Summary shall be generated by extracting appropriate text from the current draft Toxicological Review (i.e., the draft that reflects revisions in response to external peer review comments). Little new writing will be required. The WAM will provide the Contractor with the appropriate draft of the Toxicological Review to use in developing the IRIS Summary. The Contractor shall submit the draft IRIS Summary to the WAM for review.

The WAM will provide to the Contractor EPA's comments on the draft IRIS Summary. The Contractor shall revise the IRIS Summary based on EPA's comment and submit the revised final draft IRIS Summary to the WAM.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

Task	Deliverable Due Date
Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan and QAPP	15 days after award
Task 3: Update and Quality Assurance of Evidence Tables	No more than 20 days after discussion with WAM
Task 4: Technical Editing of the Draft Toxicological Review of Hexavalent Chromium and IRIS Summary	No more than 20 days after receipt of the draft Hexavalent Chromium Toxicological Review and no more than 10 days after receipt of the IRIS Summary from WAM
Task 5: Updates to Literature Search	For each update, no more than 30 days after initiation of literature search
Task 6: Maintenance of the HERO Database for Hexavalent Chromium Literature	To be performed concurrent with literature search updates

Task	Deliverable Due Date
Optional Task 7: Preparation of Exposure-Response Arrays	No more than 30 days after discussion with WAM. If arrays are developed for multiple health effect categories, arrays for individual health effects should be provided to the WAM as they are completed
Optional Task 8: Preparation of an Absorption, Distribution, Metabolism, and Excretion Synthesis	Draft – 60 days after discussion with WAM; Revision – 14 days after receiving WAM comments
Optional Task 9: Synthesis of the Evidence for Selected Health Effects	45 days after discussion with the WAM. If synthesis sections are developed for multiple health effect categories, sections for individual health effects should be provided to the WAM as they are completed
Optional Task 10: Support in Addressing Comments on the Toxicological Review following Various Review Steps	To be determined based on the nature of the Contractor support required
Optional Task 11: Preparation of IRIS Summary	7 days after final draft Toxicological Review is provided to the Contractor by EPA

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Catherine F. Gibbons, PhD
Telephone: 703-603-0704
Fax: 703-347-8689
e-mail: gibbons.catherine@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Two Potomac Yard (N-7215)
2733 S. Crystal Drive
Arlington, VA 22202

Alternate WAM:

Susan Rieth
Telephone: 703-347-8582
Fax: 703-347-8689
e-mail: rieth.susan@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Two Potomac Yard (N-7811)
2733 S. Crystal Drive
Arlington, VA 22202

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-19

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Hexavalent Chromium
	Base X Option Period Number	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues & Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:
Contractor shall not commence work on optional tasks unless notified to do so, in writing, by EPA WA-COR.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$146,850.00	1,537
Total:	$152,850.00	1,537

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 12/03/2014	$146,850.00	1,537
Cumulative Approved:	$152,850.00	1,537

Work Assignment Manager Name: Catherine Gibbons (Signature) (Date)	Branch/Mail Code: Phone Number: 703-603-0704 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107